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SUBMISSION OF APPEAL BRIEF with check
APPEAL BRIEF in triplicate.

Dale Lovercheck
Patent Attorney Reg. No. 28638

Physically delivered to the United States Post Office, Elwyn, Pennsylvania by:
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Patent Attorney Reg. No. 28638

PATENT
ANAL-VIT

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

PATENT APPLICATION: DALE R. LOVERCHECK

Serial No. 09/900,647 Art Unit:1617

Filed: July 7, 2001 Examiner: Hui, San Ming R.

For: UNIT DOSE OF MATERIAL IN SYSTEM AND METHOD

The Commissioner for Patents
Alexandria, Virginia. 22313-1450

SUMISSION OF APPEAL BRIEF

Applicant hereby submits the APPEAL BRIEF in triplicate.

The fee for filing the APPEAL BRIEF is $165.

My check in the amount of the fee is enclosed.

Respectfully submitted,

DALE R. LOVERCHECK

July 8, 2004

Patent Attorney Reg. No. 28638

Telephone number: (610) 872-5150

PATENT
ANAL-VIT

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APPEAL BRIEF

REAL PARTY IN INTEREST

Dale R. Lovercheck is the real party in interest.

RELATED APPEALS AND INTERFERENCES

There are no related appeals and interferences.

STATUS OF THE CLAIMS

Claims 1-25, 31-32, 36, 47, 56, 75 and 84 have been canceled.

Claims 26-30, 33-35, 37-46, 48-55, 57-74, 76-83, 85-94 are pending.

Claims 49, 55, 57, 58, 62, 63, 70, 85 and 88-90 have been withdrawn from consideration as being drawn to non-elected species.

STATUS OF AMENDMENTS

The Amendment under 37 CFR 1.116 filed March 1, 2004 has not been entered.

The Amendment under 37 CFR 1.116 filed April 1, 2004 has been entered.

SUMMARY OF THE INVENTION

The invention provides a method of indication for a unit dose of an orally consumable material for relief of discomfort and supplementing nutrition, comprising: enclosing a unit dose of orally consumable material in an enclosure having indications, the unit dose comprising a predetermined amount of discomfort reliever, and a predetermined amount of at least one nutritional supplement selected from the group consisting of vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin E, vitamin K, folic acid, niacin, biotin, beta-carotene, pantothenic acid, calcium, chlorine, chromium, copper, iodine, iron, manganese, molybdenum, phosphorus, potassium, and zinc, [pages 1,3, 6-7, and 10 first complete paragraph and Examples

2, 4, 5A, 5B, 5C, 11, 14, and 15-18 of the original specification] and

the indications indicating the amount of the discomfort reliever in the unit dose, the indications indicating the amount of the nutritional supplement in the unit dose, [as see page 3, second full paragraph of the original specification]

the indications indicating the nutritional supplement for supplementing nutrition, [as see page 3, second full paragraph of the original specification] and

the indications indicating the discomfort reliever as being for relief of at least one discomfort selected from the group consisting of aches, pain, fever, running nose, sneezing, itching of nose, itching of throat, itchy watering eyes due to upper respiratory allergy, insomnia, sleepiness, fatigue and drowsiness [as see page 5, first full paragraph of the original specification].

ISSUES

Whether Claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69, 71-84, 86-87 and 91-94 are unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda, Yeh et al in view of Krause.

GROUPING OF CLAIMS

Claims 48, 50-54, 56, 59-61, 64-69, and 71-81 are grouped together as they require a unit dose of discomfort reliever in an enclosure having indications indicating supplementing nutrition. These claims do not stand or fall together.

Claims 26-30, 33-35, 37-46, 82-84, 86-87 and 91-94 are grouped together as they require a unit dose of discomfort reliever in an enclosure having indications indicating a percent of a daily value for a nutritional supplement in the unit dose. These claims do not stand or fall together.

ARGUMENT

LACK OF ANY TEACHING FOR THE COMBINATION OF REFERENCES

The court has stated that a teaching is required in the references to suggest the combination thereof for a proper combination of references, In re Sernaker 702 F2d 989, 217 U.S.P.Q. 1 (CAFC, 1983). No teaching is provided by SS Pharmaceutical, Tsunoda, Yeh et al or Krause to suggest their combination, so the combination is improper.

Appellant's invention provides a method of providing a unit dose of discomfort reliever and nutritional supplement in an enclosure having indications indicating

supplementing nutrition. SS Pharmaceutical, Tsunoda, and Yeh et al disclose pharmaceutical medication (cold, menstruation and/or periodontal). They do not disclose supplementing nutrition, food, nutrition labeling for processed food or including any amount of antioxidant and/or synergistic vitamins to supplement nutrition or beyond that, which is part of a pharmaceutical medication. Neither SS Pharmaceutical, Tsunoda nor Yeh et al disclose an amount of vitamin C, a percent daily value or any intention of supplementing nutrition.

Krause discloses nutrition labeling for processed food, but does not disclose pharmaceutical medications or discomfort relief. Since, SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose food or any intention of supplementing nutrition, and Krause does not disclose pharmaceutical medication or discomfort relief, there is no teaching to suggest their combination. Thus, the combination of SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is improper, because nothing is disclosed or taught in them to suggest their combination, In re Sernaker. Accordingly, the rejection of Claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda and Yeh et al in view of Krause is erroneous.

The court has stated that a teaching or suggestion to make the claimed combination and a reasonable expectation of success must both be found in the prior art, not in Appellant's disclosure In re Vaeck 947 F 2d 488, 20 USPQ2d 1438 (Fed. Cir 1991). The prior art rejection is improper because it lacks both a teaching to make the claimed combination and a reasonable expectation of success. The combination of SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is improper, because nothing is taught in them to suggest their combination, In re Sernaker. And, there is not a reasonable expectation of success for indicating supplementing nutrition, in labeling products based on SS Pharmaceutical, Tsunoda, and Yeh et al, since they do not disclose any intention to supplement nutrition. Also, they are not properly combined with Krause, as discussed above. Additonally, they teach away from supplementing nutrition, as discussed below. So, there is no reasonable expectation of success in arriving at a method of providing a unit dose of discomfort reliever and nutritional supplement in an enclosure having indications for

supplementing nutrition, as claimed by Appellant. Accordingly, the rejection of Claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda and Yeh et al in view of Krause is erroneous.

The Examiner states that one cannot show nonobviousness by attacking references individually where the rejection is based on a combination of references, In re Keller, 642 F.2d 413, 425, 208 USPQ 871 881 (CCPA 1981) and In re Merck & Co. 231 USPQ 375, 380 (CAFC, 1986) (page 6 of the Final Rejection). But, the rejection is not based on a proper combination of references. The test for obviousness is what the properly combined teachings of the references would have suggested to those of ordinary skill in the art, In re Keller. So, the applied combination of references is not proper, because it lacks a suggestion for combining the teachings of the references, as discussed above, In re Sernaker 702 F2d 989, 217 U.S.P.Q. 1 (CAFC, 1983). And, the applied combination of references is not proper, because it lacks a reasonable expectation of success, as discussed above, In re Vaeck.

The Examiner states that vitamin C is a nutritional supplement, (pages 2 and 3 of the Advisory action dated May 6, 2004). But, vitamins and minerals are not always used for nutritional supplement products. For example, they are sometimes used as antioxidants, buffering agents or inactive ingredients without any intention of supplementing nutrition. Products containing vitamin C, based on SS Pharmaceutical, Tsunoda, and Yeh et al are not nutritional supplement products, because they do not disclose any intention to supplement the diet.

An amount of vitamin or mineral intended for supplementing nutrition is needed for a product to be a nutritional supplement as disclosed at page 6 of the above captioned patent application; as claimed by Appellant; and as defined by dietary supplement labeling law, (Dietary Supplement Health and Education Act of 1994 section 3 (a)(ff) (1) Nutritional Supplements Association page 3: EXHIBIT E of the April 1, 2004 Amendment). So, amounts of vitamin or mineral, which are not intended for supplementing nutrition are not sufficient for a product to be a nutritional supplement. And, SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose an

amount of vitamin or mineral intended for supplementing nutrition. So, they do not disclose a nutritional supplement product. And, they are not properly combined with Krause, as discussed above.

Synergistic and/or antioxidant vitamin C is disclosed for reducing pain and/or inflammation, and is not disclosed as being intended to supplement nutrition in SS Pharmaceutical, Tsunoda, and Yeh et al. So, indications of supplementing nutrtion would not be included in labeling products based on them. Thus, potential consumers of such products would have the problem of not having indications indicating supplementing nutrition including the percent daily value of any vitamin and/or mineral included in them. Accordingly, a product containing vitamin C is not a nutritional supplement, when used without any intention of supplementing nutrition, as a synergist and/or antioxidant to reduce inflammation and/or pain in products based on SS Pharmaceutical, Tsunoda, and Yeh et al.

Minerals include calcium, magnesium and iron, and they are often provided in nutritional supplement products as salts and/or oxides (Lieberman and Bruning, The Real Vitamin and Mineral Book, 1997, page 138, 146 and 157: EXHIBIT A of the Supplemental Remarks filed May 19, 2004). Also, food labels include minerals and vitamins in listings of Nutrition Facts, and dietary supplement labels include minerals and vitamins in listings of Supplement Facts, (21 CFR 101.9 (c)(12-14) and 21 CFR 101.36 (e)(10)-Exhibit D, parts 1 and 2 of the Amendment filed May 19, 2004).

Prior commercial pain reliever products include salts and oxides of minerals as buffering agents and inert ingredients, (EXHIBITS A-G of the Amendment filed March 1, 2004). But, their labeling does not include names, amounts and/or percent daily values of minerals or any listing of Nutrition Facts and/or Supplement Facts. Thus, the minerals contained in their buffering agents and/or inert ingredients are not provided to supplement nutrition. So, potential consumers of such products have the problem of not knowing the name, amount or percent daily value of any mineral included in them. Thus, products containing vitamins and/or minerals are not nutritional supplements, when used without any intention of supplementing nutrition. Accordingly, products based on SS Pharmaceutical, Tsunoda, and Yeh et al are not nutritional supplement products, because they do not disclose any intention of

supplementing nutrition.

DISCOMFORT RELIEVER PRODUCTS AND NUTRITIONAL SUPPLEMENT PRODUCTS ARE DISCLOSED, REGULATED AND SOLD SEPARATELY

Prior art discomfort reliever products and nutritional supplement products are disclosed, regulated and sold separately. The disclosures of the prior art references for discomfort reliever products, such as SS Pharmaceutical, Tsunoda, and Yeh et al, are separate from the disclosures of the prior art references for food and/or nutritional supplement products, such as Krause. Dietary supplements are products intended to supplement the diet that contain a vitamin or mineral (EXHIBIT E of the April 1, 2004 Amendment). SS Pharmaceutical, Tsunoda, and Yeh et al disclose drug products. They do not disclose any intention of supplementing nutrition. So, they do not disclose nutritional supplement products, because dietary supplements are products intended to supplement the diet. And any supplementing of nutrition would be unintended in products based on them. Krause discloses processed food, but not drugs. So, discomfort reliever products and nutritional supplement products are disclosed separately and distinctly in the prior art references. Thus, the discomfort reliever disclosures of SS Pharmaceutical, Tsunoda, and Yeh et al are separate and distinct from the food disclosure of Krause, and would lead those of ordinary skill in the art to separate and distinct products, enclosed in distinctively labeled separate containers.

Drug labeling law is separate and distinct from food and nutritional supplement labeling laws. Drug labeling law includes sample labels for Drug Facts, 21 CFR 201; 21 CFR 101: 21 CFR 201.66 - Exhibit G of the Amendment filed March 1, 2004. But, they do not mention food and/or nutritional supplements or their labeling laws. Similarly, food and/or dietary supplement labeling laws includes sample labels for Nutrition Facts and Supplement Facts, 21 CFR 101.9 (c)(12-14) and 21 CFR 101.36 (e)(10)-Exhibit D, parts 1 and 2 of the Amendment filed May 19, 2004. But, they do not mention drugs or drug labeling law. So, the law for labeling drugs is separate and distinct from the laws for labeling food and dietary supplements.

Prior art commercial discomfort reliever products are sold separately from

prior art commercial nutritional supplement products. They are sold as separate and distinct products having distinctively labeled separate containers, such as those disclosed in the above captioned patent application at pages 29-31; EXHIBITS A-G of the Amendment filed March 1, 2004; and Exhibit B of the Amendment filed May 19, 2004. Labels for commercial pain reliever products have a listing under Drug Facts, (EXHIBITS A-G of the Amendment filed March 1, 2004). But, they do not have a listing of Supplement Facts. By contrast, labels for nutritional supplement products have a listing under Supplement Facts, (Exhibit B of the Amendment filed May 19, 2004). But, they do not have a listing of Drug Facts. Thus, prior commercial discomfort reliever products and nutritional supplement products are sold as separate and distinct products having distinctively labeled separate containers.

And, when vitamins and/or minerals are included in prior commercial pain reliever products, they are not included for supplementing nutrition. Thus, they are not nutritional supplement products. So, supplementing nutrition is not disclosed in their labeling.

For example, calcium, magnesium and iron are minerals, which are sometimes provided in the form of salts and/or oxides, (Lieberman and Bruning, The Real Vitamin and Mineral Book, 1997, page 138, 146 and 157). And, prior commercial pain reliever products include buffering agents and/or inactive ingredients that contain these minerals in the form of salts and/or oxides: calcium carbonate, magnesium carbonate, magnesium oxide, magnesium stearate and/or iron oxide, (Advil, Motrin, Aleve, Tylenol, Excedrin or Bufferin: EXHIBITS A-G of the Amendment filed March 1, 2004). But, labeling for prior commercial pain reliever products does not indicate the names or amounts of minerals, their percent daily values or indications indicating supplementing nutrition. So, salts and oxides of minerals, as inert ingredients and/or buffering agents are not intended for supplementing nutrition in prior commercial pain reliever products. Thus, prior commercial pain reliever products are not nutritional supplement products. And, consumers do not know the percent daily values of the minerals consumed in them.

PROBLEMS OF IRREGULAR USE OF ESSENTIAL VITAMINS AND MINERALS

The Examiner stated that there is no evidence that others knew of the problems or worked on them (Advisory Action dated May 6, 2004, page 2, first paragraph). But, both vitamins and minerals are known to be essential to good health, and knowing whether we are consuming them sufficiently is a problem that is only partially solved by guidelines of recommended allowances, (Lieberman and Bruning, The Real Vitamin and Mineral Book, 1997, page 17: EXHIBIT A of the Supplemental Remarks filed May 19, 2004). This is objective evidence that the art recognized a need for consumption of vitamins and minerals. And, that the art recognized a need to know the sufficiency of vitamins and minerals consumed for nutritional needs MPEP 716.04. Prior art commercial nutritional supplement products labeled with Supplement Facts are additional objective evidence that the art recognized a need for their consumption, and a need to know the percent daily values of vitamins and minerals consumed. These include multiple vitamin and mineral nutritional supplement products such as, One A Day Maximum: Exhibit B of the Amendment filed May 19, 2004, and those nutritional supplement products listed in Table VI, center column pages 30-31 of the above captioned patent application, MPEP 716.04.

The evidence indicates that for many people there has been a long felt need for regular use of nutritional supplements, COUNCIL FOR RESPONSIBLE NUTRITION, The Benefits of Nutritional Supplements, Executive summary 2001 (see page 1, last paragraph of the above captioned patent application). This is objective evidence that the art recognized a need for regular consumption of nutritional supplement products, MPEP 716.04. Thus, the needs for vitamins and minerals, and regularity in their consumption are well known.

Prior art problems of irregular use stem from consumers not routinely finding and consuming nutritional supplements. These problems are partially from consumers not knowing the names and percent daily values of vitamins and/or minerals consumed in prior pain reliever products. These problems are solved by Appellant's invention.

FAILURE TO RECOGNIZE THE PROBLEMS SOLVED BY THE INVENTION

Long felt needs because of unsolved problems due to the failures by others to recognize and solve them, may be relevant evidence of nonobviousness, when they are solved by the invention, Graham v Deere 383 US 1, 148 USPQ 459 (1966). The evidence indicates that for many people there has been a long felt need for regular use of nutritional supplements, COUNCIL FOR RESPONSIBLE NUTRITION, The Benefits of Nutritional Supplements, Executive summary 2001, (see page 1, last paragraph of the above captioned patent application). This recognized need for regular use of nutritional supplements, is satisfied by consuming a discomfort reliever and a nutritional supplement according to the method of Appellant's invention. It solves the problems of the prior art of not regularly finding and consuming vitamins and minerals, and the consumers problem of needing to know names and percent daily values of vitamins and/or minerals consumed in discomfort reliever products. The prior art fails to recognize these needs and to solve these problems. Krause does not recognize the long felt need for regular use of nutritional supplements, and does not solve the problem of their irregular use. Krause discloses labeling for food, and does not disclose relieving a discomfort, (see page 277, last paragraph). SS Pharmaceutical, Tsunoda, and Yeh et al do not recognize or solve the consumer's problem of needing to know the percent daily value of the vitamins and/or minerals consumed.

Thus, these problems remained unsolved after the disclosures of SS Pharmaceutical, Tsunoda, and Yeh et al and Krause. And, there is no teaching or suggestion in them for their combination, as discussed above. After the disclosures of SS Pharmaceutical, Tsunoda, and Yeh et al and Krause the long felt needs remained for both routinely consuming nutritional supplements, and knowing the percent daily value of the vitamins and mineral consumed in discomfort reliever products. These problems, remained unsolved, because of the failures by them and others to recognize these problems. These problems are solved by the invention. This is relevant evidence of nonobviousness, Graham.

The court has stated that a teaching or suggestion to make the claimed combination and a reasonable expectation of success must both be found in the

prior art, not in Appellant's disclosure In re Vaeck 947 F 2d 488, 20 USPQ2d 1438 (Fed. Cir 1991). The prior art problems of the consumer needing to know the names and percent daily values of vitamins and/or minerals consumed in discomfort reliever products were not recognized, as discussed above. So, there was not a reasonable expectation of success in solving them. Appellant solves them by a method of providing a unit dose of discomfort reliever and nutritional supplement in an enclosure having indications indicating supplementing nutrition. Also, the applied prior art is not properly combined, as discussed above. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

LONG FELT NEED SATISFIED COMMERCIALLY

The consumer's problems remained unsolved after disclosure of ibuprofen and synergistic and/or antioxidant vitamin C by SS Pharmaceutical, Tsunoda and Yeh et al and the disclosure of nutrition labeling by Krause. For example, calcium, magnesium and iron are minerals, which are sometimes provided in the form of salts and/or oxides, (Lieberman and Bruning, The Real Vitamin and Mineral Book, 1997, page 138, 146 and 157). And, prior commercial pain reliever products include buffering agents and/or inactive ingredients that contain these minerals in the form of salts and/or oxides, (EXHIBITS A-G of the Amendment filed March 1, 2004). But, there is no indication of mineral names, their amounts and/or their percent daily values in labeling for these prior commercial pain reliever products. So, the consumer must remember to find and consume nutritional supplement products from separate distinctively labeled containers to know that sufficient nutritional supplements are being consumed. This is objective evidence that the consumer's problems remained unsolved after the disclosures of ibuprofen and synergistic and/or antioxidant vitamin C of SS Pharmaceutical, Tsunoda and Yeh et al and the nutrition labeling disclosure of Krause.

Appellant's invention solves these problems. Appellant's invention provides nutritional supplements regularly for consumers having persistent discomfort by their use of a method of providing a unit dose of discomfort reliever in an enclosure

having indications indicating supplementing nutrition. The fact that a problem's solution is simple or appears so when viewed in retrospect does not mean that the solution was obvious when it was conceived; to the contrary it is evidence of patentable invention, Colt industries Operating Corp v Index-Werke KG Hahn & Tessky (DC Dist Col) 206 USPQ 991.

Beginning in 2002, a long felt need for regular consumption of a nutritional supplement was satisfied commercially. It was satisfied by a unit dose of a discomfort reliever in an enclosure having indications indicating supplementing nutrition, (Bayer Consumer Care and Tony Raines Race for Women's Health in New Hampshire, page 1 first paragraph- EXHIBIT B of the April 1, 2004 Amendment).

SUPERIOR RESULTS

Only half as many unit dose compositions and containers and half as much storage space is needed by Appellant's invention compared to the distinctively labeled, separately enclosed discomfort reliever products and nutritional supplement products of the prior art. The consumer saves the time and expense that would otherwise be needed to purchase, consume and/or maintain the distinctively labeled, separately enclosed discomfort reliever products and nutritional supplement products of the prior art. Appellant's invention adds the ability to self-regulate consumption of nutritional supplements while alleviating a discomfort. There has been a long felt need for Appellant's invention, which provides a method of providing a unit dose of discomfort reliever and nutritional supplement in an enclosure having indications indicating supplementing nutrition. Use of Appellant's invention regularly provides the same discomfort relief and the same ability to self-regulate consumption of nutritional supplements, as does opening and closing twice as many containers, and consuming twice as many unit dose compositions of the separate discomfort reliever products and nutritional supplement products of the prior art.

Benefits of Appellant's invention, which are not provided by the applied prior art include: a method of providing a unit dose of discomfort reliever in an enclosure having indications indicating a percent daily value for a nutritional supplement in the unit dose. This is practically significant compared to the applied prior art. It

provides the user with discomfort relief and an additional indication: a percent daily value for the nutritional supplement in each unit dose. With this indication the user has the ability to self regulate consumption of nutritional supplements while alleviating a discomfort. It enables the consumer to regularly consume only half as many unit dose compositions from only half as many containers. And, it retains all of the benefits of the prior art. It results in superior convenience and superior savings in unit dose compositions, containers, and storage space. The statute does not require a patentable invention to be superior Demaco Corp v F Von Langsdorff Licensing Ltd. 7 USPQ2d 1222 (Fed. Cir 1988). Thus, patentability is shown beyond the requirements of the statute, Demaco. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

The Examiner states that there is no data of superior results (Advisory Action dated March 24, 2004, paragraph 5 continuation). But, data of superior results is shown in the elimination of half of the number of unit dose compositions and half of the number of containers required by the prior art. This results in saving the unit dose compositions, containers and storage space. Only one unit dose composition in one container is needed for the method claimed by Appellant, rather than two separate distinctively labeled containers enclosing two different unit dose compositions needed by the prior art.

So, data of superior results of Appellant's invention are shown by omission of half of the number of unit dose compositions and half of the number of containers, while retaining all of their benefits and functions. Thus, a unit dose of discomfort reliever product in one container and a separate unit dose of nutritional supplement product in a separate distinctively labeled container are replaced by one unit dose of discomfort reliever and nutritional supplement in one container. Data of superior results are shown for Appellant's invention by saving unit dose compositions, containers and storage space. The consumer purchases, uses and maintains only half as many unit dose compositions in only half as many containers. Thus, patentability is shown beyond the requirements of the statute, Demaco. Accordingly,

the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

By using Appellant's invention, consumers regularly consume nutritional supplements, while relieving their discomfort without having to routinely remember to find and consume them. By, contrast consumers of prior commercial pain relievers, must regularly remember to find and consume nutritional supplements from separate distinctively labeled containers.

OMISSION OF AN ELEMENT WITH RETENTION OF THE ELEMENT'S FUNCTION IS AN INDICIA OF UNOBVIOUSNESS

Omission of an element with retention of the element's function is an indicia of unobviousness, In re Edge, 359 F2d 896, 149 USPQ 556 (CCPA, 1966), and MPEP 2144.04, II, B. Appellant's invention omits half of the number of unit dose compositions and half of the number of containers of the separate pain reliever products and nutritional supplement products of the prior art. While the functions of both products are retained in one product. Thus, a unit dose of discomfort reliever product in one container and a separate unit dose of nutritional supplement product in a separate distinctively labeled container is replaced by one unit dose of discomfort reliever and nutritional supplement product in one container. So, Appellant's invention has indicia of unobviousness. Since, it omits half of the number of unit dose compositions and half of the number of containers required by the prior art with retention of all of their functions, In re Edge. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

THE APPLIED REFERENCES TEACH AWAY FROM THE INVENTION

Portions of a reference teaching away from the claimed invention must be considered, Bausch & Lomb Inc v Barnes-Hind/Hydrocurve, Inc, 796 F2d 443; 230 USPQ 416 (CAFC 1986). Portions of SS Pharmaceutical, Yeh et al and Tsunoda teach away from the claimed invention. So they must be considered.

Each vitamin is essential to good health regardless of how much of anything

else is consumed, Lieberman and Bruning, The Real Vitamin and Mineral Book, 1997, page 17: EXHIBIT A of the Supplemental Remarks filed May 19, 2004. Thus, a vitamin cannot be replaced by another vitamin, a portion of a vitamin or a compound that is not a vitamin. Yeh et al teach away from the function of supplementing nutrition and its indication by disclosing that a vitamin can be replaced by another vitamin, by portion of a vitamin or by a compound that is not a vitamin. And, by not disclosing any amount of an antioxidant, or any percent daily value for an antioxidant, SS Pharmaceutical, Yeh et al and Tsunoda teach away from indicating supplementing nutrition and the invention.

A vitamin cannot replace the nutrition supplementing function of another vitamin. Because, each vitamin is essential to good health regardless of how much of anything else is consumed, Lieberman and Bruning, The Real Vitamin and Mineral Book, 1997, page 17: EXHIBIT A of the Supplemental Remarks filed May 19, 2004. So, by disclosing that ascorbic acid functions the same as vitamin A, Yeh et al teach away from the function of supplementing nutrition and its indication, column 2, lines 4-7 and 48-52. Thus, no indication of supplementing nutrition would be provided for antioxidant and/or synergistic ascorbic acid as part of a pain reliever product based on Yeh et al.

A portion of a vitamin cannot replace a vitamin and its nutrition supplementing function. Because, each complete vitamin is essential to good health regardless of how much of anything else is consumed, Lieberman and Bruning, The Real Vitamin and Mineral Book, 1997, page 17: EXHIBIT A of the Supplemental Remarks filed May 19, 2004. And, alpha-tocopherol is one of the eight compounds that make up vitamin E, APPENDIX B, page 81. So, by disclosing that alpha-tocopherol, functions the same as ascorbic acid or vitamin A, Yeh et al teach away from the function and indication of supplementing nutrition and the invention, column 2, lines 4-7 and 48-52. And, by not disclosing seven of the eight compounds that make up vitamin E, Yeh et al teach away from the function and indication of supplementing nutrition. Thus, no indication of supplementing nutrition would be provided for antioxidant and/or synergistic ascorbic acid as part of a pain reliever product based on Yeh et al.

A compound that is not a vitamin cannot replace a vitamin and its nutrition supplementing function. Because, each vitamin is essential to good health regardless of how much of anything else is consumed, Lieberman and Bruning, The Real Vitamin and Mineral Book, 1997, page 17: EXHIBIT A of the Supplemental Remarks filed May 19, 2004. And, antioxidants other than vitamins are not vitamins. So, products based on them are not nutritional supplement products. By disclosing that an antioxidant vitamin (vitamin A) functions the same as an antioxidant other than a vitamin, Yeh et al teach away from the function of supplementing nutrition and its indication, column 2, lines 48-52. Because, they are teaching that neither vitamin A, nor anything else is intended to supplement nutrition. And, they are teaching that the lack of anything that could function as a vitamin is suitable for its purposes. Thus, Yeh et al teach away from the function of supplementing nutrition and its indication. So, no indication of supplementing nutrition would be provided for antioxidant and/or synergistic ascorbic acid as part of a pain reliever product based on Yeh et al.

Yeh et al do not disclose vitamin names (vitamin E and vitamin C), their amounts and their percent daily values. Alpha-tocopherol and ascorbic acid are preferred antioxidants disclosed by Yeh et al column 2, lines 4-7 and 48-51. Vitamin C is available as ascorbic acid, and alpha-tocopherol is only one of the eight compounds that make up vitamin E, APPENDIX B, pages 81 and 126.

Thus, by not disclosing vitamin names vitamin E and vitamin C, their amounts or their percent daily values, Yeh et al teach away from indicating supplementing nutrition, and Appellant's invention. So, no indication of supplementing nutrition would be provided for antioxidant and/or synergistic ascorbic acid as part of a pain reliever product based on Yeh et al. And, a consumer of a product based on Yeh et al does not know when adequate amounts of vitamins and/or minerals are consumed.

Neither SS Pharmaceutical, Tsunoda, nor Yeh et al disclose an amount of vitamin C, or a percent daily value. A reference daily intake of vitamin C is an amount (60 milligrams) recommended for daily consumption to supplement nutrition, as see Krause pages 277-278 and 21 CFR 101.9(c)(8)(iv): Exhibit D, part 1 of the

Supplemental Remarks filed May 19, 2004. And percent daily value is determined from an amount (21 CFR 101.36 (b)(iii)(B).

Thus, by not disclosing any amount or a percent daily value for any antioxidant vitamin SS Pharmaceutical, Tsunoda, and Yeh et al teach away from the function of supplementing nutrition and its indication. Furthermore, by disclosing antioxidants to reduce pain, inflammation and/or periodontal disease, rather than for supplementing nutrition, SS Pharmaceutical, Tsunoda, and Yeh et al teach away from the function of supplementing nutrition and its indication. So, no indication of supplementing nutrition would be provided for antioxidant and/or synergistic ascorbic acid as part of a pain reliever product based on SS Pharmaceutical, Tsunoda, and Yeh et al. And, the consumers of products based on SS Pharmaceutical, Tsunoda, and Yeh et al do not know the amount of any antioxidant vitamins that may be consumed, or their percent daily values.

These prior art teachings away from the invention, support a conclusion of nonobviousness, Dow Chemical Co v US,18 USPQ2d 1657, 1662 (US Claims Ct, 1990). Portions of a reference teaching away from the claimed invention must be considered, Bausch & Lomb Inc v Barnes-Hind/Hydrocurve, Inc, 796 F2d 443; 230 USPQ 416 (CAFC 1986). Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

The Examiner states that it is unclear how the disclosure in Yeh et al of antioxidant and/or synergistic vitamin C as part of a pain reliever essentially teaches away from the invention, (page 9 of the Final Rejection). By not disclosing the vitamin name, amount or percent daily value of ascorbic acid antioxidant Yeh et al teach away from indicating supplementing nutrition and the invention.

By disclosing alpha-tocopherol, ascorbic acid, vitamin A and other antioxidants as equivalent to each other, Yeh et al are teaching that a vitamin can be replaced by another vitamin, by a small fraction of a vitamin, or by a compound that cannot function as a vitamin, column 2, lines 48-52. But, the nutrition supplementing function of a vitamin cannot be replaced in this manner. So, they are teaching away from the function and indication of supplementing nutrition and the

invention. And, by disclosing the functions of reducing pain, inflammation and/or periodontal disease, rather than the function of supplementing nutrition, Yeh et al teach away from indicating supplementing nutrition and the invention. These portions of the reference teach away from indicating supplementing nutrition and the claimed invention, and must be considered, Bausch & Lomb Inc.

In general a reference will teach away, if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the Appellant, In re Gurley 27 F3d 551; 31 USPQ 2d 1130, 1132 (CAFC, 1994). The result sought by claims 48, 50-54, 56, 59-61, 64-69, and 71-81 is a method of providing a unit dose of discomfort reliever in an enclosure having indications indicating supplementing nutrition. As discussed above, none the applied prior art references discloses this result. SS Pharmaceutical, Tsunoda and Yeh et al teach away from it, and they are not properly combined with Krause. So, they are unlikely to produce the result, In re Gurley. Accordingly, the rejection of claims 48, 50-54, 56, 59-61, 64-69, and 71-81 as obvious over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

Indicating a percent daily value for a nutritional supplement in a unit dose of a discomfort reliever is a result sought in Claims 26-30, 33-35, 37-46, 82-84, 86-87 and 91-94. As discussed above, none the applied prior art references discloses this result. SS Pharmaceutical, Tsunoda and Yeh et al teach away from it, and they are not properly combined with Krause. So, they are unlikely to produce the result, In re Gurley. Accordingly, Claims 26-30, 33-35, 37-46, 82-84, 86-87 and 91-94 are not prima facie obvious over the combination of SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause.

Indicating from one to fifty percent daily value of a nutritional supplement in a unit dose of a discomfort reliever is a result sought in Claims 33, 86 and 94. As discussed above, none the applied prior art references discloses this result. SS Pharmaceutical, Tsunoda and Yeh et al teach away from it, and they are not properly combined with Krause. So, they are unlikely to produce the result, In re Gurley. Accordingly, Claims 33, 86 and 94 are not prima facie obvious over the combination of SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause.

Indicating instructions for consuming a unit dose of a discomfort reliever for supplementing nutrition is a result sought in claim 79. As discussed above, none the applied prior art references discloses this result. SS Pharmaceutical, Tsunoda and Yeh et al teach away from it, and they are not properly combined with Krause. So, they are unlikely to produce the result, In re Gurley. Accordingly, claim 79 is not prima facie obvious over the combination of SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause.

FEATURES NOT DISCLOSED CANNOT BE MEANINGFULLY CONSIDERED

The court has held that the absence from the applied references of an explicit requirement of the claims makes the rejection improper, In re Evanega 4 USPQ 2nd 1249 (CAFC, 1987). And, all of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. v Westinghouse Elec. Corp. 3 USPQ2d 1321, 1324-25 (Fed. Cir, 1987). Indications indicating supplementing nutrition in a method of providing a unit dose of a discomfort reliever and nutritional supplement in an enclosure are explicitly required in Claims 48, 50-54, 56, 59-61, 64-69, and 71-81. Neither, SS Pharmaceutical, Tsunoda, Yeh et al nor Krause discloses this feature. And they are not properly combined, as discussed above. All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. And, the absence from all of the applied references of this explicit requirement of the claims makes the rejection improper, In re Evanega. Accordingly, the rejection of claims 48, 50-54, 56, 59-61, 64-69, and 71-81 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause, is erroneous and improper.

Indications indicating a percent daily value for a nutritional supplement in a unit dose of discomfort reliever in a method of providing the unit dose in an enclosure are explicitly required by Claims 26-30, 33-35, 37-46, 82-84, 86-87 and 91-94. Neither, SS Pharmaceutical, Tsunoda, Yeh et al nor Krause discloses this feature. And they are not properly combined, as discussed above. All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. And, the absence from all of the applied references of this explicit requirement of the claims makes the rejection improper, In re Evanega. Accordingly, the rejection of claims

26-30, 33-35, 37-46, 82-84, 86-87 and 91-94 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause, is erroneous and improper.

Indications indicating from one to fifty percent daily value of a nutritional supplement in a method of providing a unit dose of discomfort reliever in an enclosure, are explicitly required by Claims 33, 86 and 94. SS Pharmaceutical, Tsunoda, and Yeh et al and Krause do not disclose this feature. And they are not properly combined, as discussed above. All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. And, the absence from all of the applied references of this explicit requirement of the claims makes the rejection improper, In re Evanega. Accordingly, the rejection of claims 33, 86 and 94 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause, is erroneous and improper.

Indications indicating instructions for consuming a unit dose for supplementing nutrition in a method of providing the unit dose of discomfort reliever in an enclosure are explicitly required by Claim 79. Neither, SS Pharmaceutical, Tsunoda, Yeh et al nor Krause discloses this feature. And, they are not properly combined, as discussed above. All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. And, the absence from all of the applied references of this explicit requirement of the claim makes the rejection improper, In re Evanega. Accordingly, the rejection of claim 79 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause, is erroneous and improper.

THE COMBINATION OF REFERENCES IS A HINDSIGHT RECONSTRUCTION OF APPELLANT'S INVENTION

One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention, In re Fine, 837 F2d 1071, 1075, 5 USPQ 2d 1598, 1600 (Fed. Cir. 1988). And, a proper combination of references cannot be based on forbidden hindsight, In re Rouffet 47 USPQ2d 1453, 1458 (CAFC, 1998). Disclosure of food labeling in Krause is isolated from disclosures of cold medication of SS Pharmaceutical, menstruation medication of

Tsunoda, and periodontal medication of Yeh et al. The rejection is erroneous because it relies upon hindsight reconstruction picking and choosing among disclosures in medication prior art, and isolated disclosures in food labeling prior art to depreciate the claimed invention. It is legal error to use the inventor's patent specification teaching of both a novel and nonobvious invention as though it were prior art in order to make claims appear to be obvious In re Pleuddemann, 901 F2d 823, 828, 15 USPQ 2d 1738, 1742 (Fed. Cir 1990). In constructing the rejection the Examiner combines SS Pharmaceutical, Tsunoda, Yeh et al and Krause without any teaching in the references for the combination thereof. The Examiner has made legally erroneous use of Appellant's patent specification teaching of both a novel and nonobvious invention as though it were prior art in order to make claims appear to be obvious In re Pleuddemann. So, the combination of SS Pharmaceutical, Tsunoda, Yeh et al and Krause of the rejection is legal error.

The Examiner states that a reconstruction is proper if it takes into account only knowledge, which was within the ordinary skill at the time of the invention, and does not include knowledge gleaned from Appellant's disclosure, see In re McLaughlin 170 USPQ 209 (CCPA 1971), (page 7 of the Final Rejection). But, the reconstruction of the Final rejection takes into account more knowledge, than was within the ordinary skill at the time of the invention. And it includes knowledge gleaned from Appellant's disclosure. Since, there is no teaching in the applied references to suggest the combination of references, they are not properly combined. So, the reconstruction is improper, In re Sernaker.

The combination of references is not proper, because it is based on forbidden hindsight, In re Rouffet. None of the applied references discloses indications indicating supplementing nutrition, percent daily value or instructions for supplementing nutrition for a nutritional supplement in a unit dose of discomfort reliever in a method of providing the unit dose in an enclosure, as claimed by Appellant. So, the reconstruction is insufficient as it omits these features of the invention, when it takes into account only knowledge, which was within the ordinary skill at the time of the invention. The reconstruction of the Final rejection is improper because it gleans this knowledge from Appellant's disclosure, In re

McLaughlin. All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. v Westinghouse Elec. Corp. 3 USPQ2d 1321, 1324-25 (Fed. Cir, 1987). Thus, the rejection does not meaningfully consider all of the limitations of the claims, Perkin – Elmer Corp. And, the combination of references is not proper, because it is based on forbidden hindsight, In re Rouffet. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

FOR A DRUG PRODUCT TO BE A NUTRITIONAL SUPPLEMENT IT MUST CONTAIN A VITAMIN OR MINERAL INTENDED TO SUPPLEMENT NUTRITION

An amount of vitamin or mineral intended for supplementing nutrition is needed for a product to be a nutritional supplement as disclosed at page 6 of the above captioned patent application; as claimed by Appellant; and as defined by dietary supplement labeling law, (Dietary Supplement Health and Education Act of 1994 section 3 (a)(ff) (1) Nutritional Supplements Association page 3: EXHIBIT E of the April 1, 2004 Amendment). And, labeling of nutritional supplements is mandated under food or dietary supplement labeling laws 21 CFR 101.9 and 101.36. So, amounts of vitamin or mineral, which are not intended for supplementing nutrition are not sufficient for a product to be a nutritional supplement product. And, SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose any amount of vitamin or mineral as being intended for supplementing nutrition. So, they do not disclose nutritional supplement products. Also, they are not properly combined with Krause, as discussed above. Accordingly, products based on SS Pharmaceutical, Tsunoda, and Yeh et al containing synergistic and/or antioxidant vitamin C, are not nutritional supplement products, because they are not intended to supplement nutrition, as discussed above.

The Examiner states that the law mandates the inclusion of indications, (page 3 of the dated May 6, 2004 and pages 5 and 7 of the Final Rejection). And, the Examiner states that ibuprofen pain reliever is a drug so its labeling is mandated under drug labeling law, while vitamin C is a nutritional supplement so its labeling is mandated under nutrition labeling law (page 4 of the Advisory action dated May 6,

2004). But, inclusion of indications is not mandated by labeling laws for vitamin C as a synergist and/or antioxidant to reduce pain and/or inflammation. And, indications indicating reducing pain and/or inflammation do not indicate supplementing nutrition, or solve the consumer's problem of needing to know the percent daily value for the amount of vitamin C consumed. Products containing vitamin C are not nutritional supplement products, if they are not intended to supplement nutrition, as discussed above. So, products based on SS Pharmaceutical, Tsunoda, and/or Yeh et al, are not nutritional supplement products, since they do not disclose any intention of supplementing nutrition, as discussed above.

Inclusion of indications is not mandated by labeling laws for vitamin C as a synergist and/or antioxidant to reduce pain and/or inflammation. SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose food or nutritional supplement or any intention of supplementing nutrition, as discussed above. So, food and dietary supplement labeling laws do not mandate inclusion of indications in labeling products based on them, 21 CFR 101.9 and 101.36. Similarly, drug labeling law does not disclose food, nutritional supplement, supplementing nutrition and/or percent daily value, 21 CFR 201.57; 21 CFR 201.60-66. Thus, it does not mandate inclusion of indications indicating supplementing nutrition and/or percent daily value. Accordingly, inclusion of these indications is not mandated by labeling laws for vitamin C as a synergist and/or antioxidant to reduce pain and/or inflammation in products based on SS Pharmaceutical, Tsunoda, and/or Yeh et al.

Indications indicating reducing pain and/or inflammation do not indicate supplementing nutrition. SS Pharmaceutical, Tsunoda, and/or Yeh et al are not properly combined with Krause, and they teach away from indicating supplementing nutrition, as discussed above. So, it is not obvious to indicate supplementing nutrition in labeling products based on them, as discussed above. They disclose vitamin C as a synergist and/or antioxidant part of a drug to reduce pain and/or inflammation. But, indications indicating reducing pain and/or inflammation do not indicate supplementing nutrition, or solve the consumer's problem of needing to know the percent daily value for the amount of vitamin C consumed. This problem is

solved by Appellant's invention.

Before indicating vitamin C as reducing pain and/or inflammation it must be approved for this use. All indications must be supported by substantial evidence based on adequate and well controlled studies 21 CFR 201.57(c)(2) and 21 CFR 314.126(b). The applied prior art does not disclose that vitamin C is clinically effective in reducing pain. And, unless an FDA review, and approval process (21 CFR 314.2) shows that vitamin C is effective to reduce pain and/or inflammation, this use is not permitted in labeling, 21 CFR 201.62. So, inclusion of indications on the label about vitamin C as a synergist and/or antioxidant to reduce pain and/or inflammation is not mandated by drug labeling law for products based on SS Pharmaceutical, Tsunoda, and/or Yeh et al.

If indications indicating supplementing nutrition and/or percent daily value are mandated for all products containing vitamins and/or minerals, then prior commercial pain reliever labeling would have them. But, these indications are not included in labeling for these products, (packaging for Advil, Motrin, Aleve, Tylenol, Excedrin or Bufferin: EXHIBITS A-G of the Amendment filed March 1, 2004). So, these indications are not mandated for all products containing vitamins and/or minerals.

For example, minerals include calcium, magnesium and iron, and they are sometimes provided in nutritional supplement products as salts and/or oxides (Lieberman and Bruning, The Real Vitamin and Mineral Book, 1997, page 138, 146 and 157: EXHIBIT A of the Supplemental Remarks filed May 19, 2004). And, prior commercial pain reliever products contain salts and/or oxides of calcium, magnesium and/or iron, as inactive ingredients and/or buffering agents, (packaging for Advil, Motrin, Aleve, Tylenol, Excedrin or Bufferin: EXHIBITS A-G of the Amendment filed March 1, 2004). But, their labeling does not disclose mineral names, mineral amounts, supplementing nutrition, percent daily value, Nutrition Facts or Supplement Facts. Thus, the law has not mandated the inclusion of indications indicating supplementing nutrition and/or percent daily value for vitamins and/or minerals, when they are not intended for supplementing nutrition in a drug product. Accordingly, the law does not mandate the inclusion of these indications for vitamin C, when it is used as an antioxidant and/or synergistically for pain relief,

in products based on SS Pharmaceutical, Tsunoda, and/or Yeh et al.

Thus, including indications indicating supplementing nutrition and/or percent daily value is not mandated by drug, food or dietary supplement labeling law for products containing vitamin C, when they are not intended to supplement nutrition, as discussed above. So, it is erroneous to assume that labeling would include an indication indicating supplementing nutrition and/or percent daily value, which is neither disclosed in the applied prior art or prior commercial labeling, nor mandated by drug, food or dietary supplement labeling laws. And, it is erroneous to assert that it would be obvious to include indications indicating supplementing nutrition and/or percent daily value in a hypothetical drug label for a theoretical product, which is not intended to supplement nutrition. Thus, the rejection is unsupported, and inconsistent with the applied prior art, the law and prior commercial labeling of record. So, it does not provide a reasonable expectation of success In re Vaeck, 947 F 2d 488, 20 USPQ2d 1438 (Fed. Cir 1991). Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda and Yeh et al in view of Krause is erroneous.

It is noted that, ibuprofen pain reliever labeling is mandated by 21 CFR 201.5. And, this mandate is complied with in labeling commercial pain relievers, Exhibits A and B of the Amendment dated March 1, 2004. And, labeling ibuprofen as a pain reliever does not enable consumers to self-regulate their consumption of vitamins and/or minerals. This problem is solved by Appellant's invention.

The Examiner states that one of ordinary skill in the art would see vitamin C is a nutritional supplement and putting information about the amount is mandated by law and obvious to one of ordinary skill in the art, as see page 3 of the Advisory action dated May 6, 2004. But, one of ordinary skill in the art would not see vitamin C as a nutritional supplement, and putting information about the amount is not mandated by law or obvious to one of ordinary skill in the art. A vitamin or mineral must be intended for supplementing nutrition for a product to be a nutritional supplement.

One of ordinary skill in the art would not see vitamin C as a nutritional supplement in product which is not intended for supplementing nutrition. An amount of vitamin or mineral intended for supplementing nutrition is needed for a product to be a nutritional supplement as disclosed at page 6 of the above captioned patent application; as claimed by Appellant; and as defined by dietary supplement labeling law, (Dietary Supplement Health and Education Act of 1994 section 3 (a)(ff) (1) Nutritional Supplements Association page 3: EXHIBIT E of the April 1, 2004 Amendment). So, amounts of vitamin or mineral, which are not intended for supplementing nutrition are not sufficient for a product to be a nutritional supplement product. And, SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose an amount of vitamin or mineral intended for supplementing nutrition. So, they do not disclose nutritional supplement products. Also, they are not properly combined with Krause, as discussed above. Accordingly, products based on SS Pharmaceutical, Tsunoda, and Yeh et al containing synergistic and/or antioxidant vitamin C, are not nutritional supplement products, because they are not intended to supplement nutrition, as discussed above.

If putting information about the amount of vitamin C was mandated by law or obvious to one of ordinary skill in the art, then prior commercial pain relievers, that contain vitamins and/or minerals would have indications about their amounts. Prior commercial pain relievers include salts and oxides of minerals as buffering agents and/or inert or inactive ingredients: Advil, Motrin, Aleve, Tylenol, Excedrin or Bufferin. (Exhibits A-G of the Amendment filed March 1, 2004. These salts and oxides of minerals are calcium carbonate, magnesium carbonate, and magnesium oxide, magnesium stearate and/or iron oxide. But, they do not indicate the name, amount or percent daily value of each mineral (iron, calcium and magnesium). Thus, they teach away from indicating supplementing nutrition. And, consumers of these prior commercial pain relievers need to consume separate distinctively labeled nutritional supplement products, to know that they are consuming sufficient amounts of nutritional supplements. This problem, remained unsolved after the disclosures of ibuprofen and synergistic and/or antioxidant vitamin C of SS Pharmaceutical, Tsunoda and Yeh et al and the nutrition labeling disclosure of Krause. This problem

is solved by Appellant's invention. Accordingly, putting information about the amount of minerals and/or vitamins is not always mandated by law or obvious to one of ordinary skill in the art.

Information about an amount of ascorbic acid and its salts is not adequate for the consumer to know when a sufficient amount of vitamin C is being consumed for supplementing nutrition. Compositions containing equal amounts of ascorbic acid and any one of its salts do not function the same for supplementing nutrition. For example, an amount of ascorbic acid and an equal amount of magnesium ascorbate do not have the same percent daily value, (Lieberman and Bruning, The Real Vitamin and Mineral Book, 1997, page 126-127 APPENDIX B). Since the equal amounts are not equivalent for supplementing nutrition, the consumer does not know when sufficient vitamin C is being consumed for supplementing nutrition, without an additional indication, such as a percent daily value.

Food and dietary supplement labeling laws do not mandate putting information about the amount of vitamin C on products based on SS Pharmaceutical, Tsunoda, and Yeh et al, because they do not disclose food or nutritional supplements. And they are not properly combined with Krause, as discussed above. They do not disclose a food, because they do not disclose protein, fat, carbohydrate, energy values, see Krause page 279, right column, first paragraph and 21 CFR 101.9 (c). And they do not disclose a nutritional supplement, because they do not disclose any intention to supplement nutrition (EXHIBIT E of the April 1, 2004 Amendment). So, they do not disclose a food or nutritional supplement. Thus, food and nutritional supplement labeling laws do not mandate labeling of products based on SS Pharmaceutical, Tsunoda, and Yeh et al.

Drug labeling law does not mandate putting information in a drug label about an amount of vitamin C to reduce pain and/or inflammation as it is not approved for these uses. Vitamin C has not been shown to be approved under drug labeling law as being effective in reducing pain and/or inflammation, 21 CFR 314.2. And, all indications must be supported by substantial evidence based on adequate and well controlled studies 21 CFR 201.57(c)(2) and 21 CFR 314.126(b). So, indicating the amount of synergistic vitamin C to reduce pain and/or inflammation is not permitted

until it is approved as effective, under 21 CFR 201.62. Accordingly, putting information in a drug label about an undisclosed amount of synergist and/or antioxidant vitamin C to reduce pain and/or inflammation is not mandated by drug, food and dietary supplement labeling laws.

An amount of vitamin C is recommended for daily consumption to supplement nutrition. And percent daily value is determined from an amount (21 CFR 101.36 (b)(iii)(B). SS Pharmaceutical, Tsunoda, and/or Yeh et al do not disclose an amount or percent daily value of vitamin C. This teaches away from indicating its amount or percent daily value. So, it would not be obvious to indicate an undisclosed amount or percent daily value of vitamin C in labeling products based on SS Pharmaceutical, Tsunoda, and Yeh et al. And, they are not properly combined with Krause, as discussed above. Also, SS Pharmaceutical, Tsunoda, and/or Yeh et al do not solve the problem of the consumer needing to know the percent daily value of the undisclosed amount of vitamin and/or mineral consumed. This problem is solved by Appellant's invention. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

The Examiner states that putting ibuprofen dosage information on drug packaging is mandated by law, page 2, second full paragraph of the Advisory action dated May 6, 2004. But, putting ibuprofen dosage information on drug packaging does not solve the consumers' problems. With ibuprofen dosage information the consumers still do not know the names, amounts and/or percent daily values of vitamins and minerals are being consumed. These problems are solved by Appellant's invention.

It is noted that, ibuprofen pain reliever labeling is mandated by 21 CFR 201.5. And, this mandate is complied with in labeling commercial pain relievers, Exhibits A and B of the Amendment dated March 1, 2004.

Also, it is noted that drug, food and dietary supplement labeling laws do not mandate indications indicating supplementing nutrition and/or percent daily value for drugs containing vitamins and minerals, which are not intended to supplement

nutrition, as discussed above. Thus, indications indicating supplementing nutrition and/or percent daily value are not included in labeling prior commercial pain relievers containing vitamins and/or minerals, as discussed above, as see Exhibits A-G of the Amendment filed March 1, 2004.

FOOD LABELING REQUIREMENTS ARE NOT MANDATORY FOR DRUG PRODUCTS WHICH ARE NOT INTENDED TO SUPPLEMENT NUTRITION

The Examiner states that for a unit dose of ibuprofen and vitamin C indicating the percent daily value is within the ordinary skill of the art based on mandatory food labeling (Krause), pages 4 and 5 of the Final Rejection. The Examiner states that the law mandates that nutritional supplement products include a recommended daily value of vitamin in the food product on the package label, (Advisory Action dated March 24, 2004, paragraph 5 continuation). And, the Examiner states that based on Krause it is mandatory for food labels to include the recommended daily allowance of vitamin C, at page 4 of the Advisory action dated May 6, 2004. But, products based on SS Pharmaceutical, Tsunoda, and Yeh et al are not nutritional supplement products, because they are not intended to supplement nutrition, as discussed above. And, indicating percent daily value or recommended daily allowance is not mandated by law for products based on SS Pharmaceutical, Tsunoda, and Yeh et al.

An amount of vitamin or mineral intended for supplementing nutrition is needed for a product to be a nutritional supplement as disclosed at page 6 of the above captioned patent application; as claimed by Appellant; and as defined by dietary supplement labeling law, (Dietary Supplement Health and Education Act of 1994 section 3 (a)(ff) (1) Nutritional Supplements Association page 3: EXHIBIT E of the April 1, 2004 Amendment). And, SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose any amount of vitamin or mineral for supplementing nutrition. So, they do not disclose a nutritional supplement product. And, they are not properly combined with Krause, as discussed above.

Indicating percent daily value or recommended daily allowance is not mandated by food and nutritional supplement labeling laws for products based on SS Pharmaceutical, Tsunoda, and Yeh et al, since they do no disclose food or dietary supplement product, 21 CFR 101.9 and 101.36. Also, they are not properly

combined with Krause, as discussed above. They do not disclose a food or a nutritional supplement product, because they do not disclose protein, fat, carbohydrate, energy values or any intention to supplement nutrition. So, food and dietary supplement labeling laws do not mandate indicating percent daily value or recommended daily allowance in labeling drug products based on SS Pharmaceutical, Tsunoda, and Yeh et al.

Percent daily value and recommended daily allowance are not disclosed in drug labeling law including sample drug labels, 21 CFR 201.57; and 201.60 to 201.66, Exhibit G of the Amendment filed March 1, 2004. So, drug labeling law does not mandate their indication. Thus, drug labeling law does not mandate their indication for synergistic and/or antioxidant vitamin C, in products based on SS Pharmaceutical, Tsunoda, and Yeh et al.

SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose indicating supplementing nutrition, percent daily value or recommended daily allowance, as discussed above. And, they teach away from supplementing nutrition, as discussed above. They are not properly combined with Krause, as discussed above. Thus, it is not obvious to include these indications in labeling for products based on SS Pharmaceutical, Tsunoda, and/or Yeh et al. Accordingly, it is not obvious to include percent daily value or recommended daily allowance in labeling for synergistic and/or antioxidant vitamin C in products based on SS Pharmaceutical, Tsunoda, and/or Yeh et al.

If indicating percent daily value or recommended daily allowance of vitamin C was mandated by law or obvious to one of ordinary skill in the art, then prior commercial pain reliever products, that contain vitamins and/or minerals would have these indications. But, they do not have them. So, consumers of prior commercial pain reliever products need to consume separate distinctively labeled nutritional supplement products, to know that they are consuming sufficient amounts of nutritional supplements.

For example, prior commercial pain reliever products include iron, calcium and magnesium in the form of salts and oxides of minerals as buffering agents and/or an inert or inactive ingredients: Advil, Motrin, Aleve, Tylenol, Excedrin and

Bufferin. (Exhibits A-G of the Amendment filed March 1, 2004). But, they do not indicate the mineral names, mineral amounts, percent daily values of minerals or recommended daily allowances of any minerals. Thus, salts and oxides of minerals, as inert ingredients and/or buffering agents are not intended for supplementing nutrition. So, Krause, and labeling laws do not mandate indicating a recommended daily allowance or percent daily value for vitamin C in labeling pain reliever products, which are not intended for supplementing nutrition. And SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose any intention of supplementing nutrition. Accordingly, Krause, and labeling laws do not mandate indicating a recommended daily allowance or percent daily value for vitamin C in labeling products based on SS Pharmaceutical, Tsunoda, and Yeh et al.

The Examiner states that Krause discloses food product mandatory labeling, page 4, second full paragraph of the Final Rejection. But, Krause and food and dietary supplement labeling laws do not disclose a discomfort reliever (21 CFR 101.36 and 21 CFR 101.9 (c)(8)(ii) and Krause). And, Krause is not properly combined with SS Pharmaceutical, Tsunoda, and Yeh et al, as discussed above. Also, SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose a food or a dietary supplement product, and teach away from supplementing nutrition, as discussed above. Thus, Krause and food and dietary supplement labeling laws do not solve the consumer's problem of irregular use of vitamins and minerals because of not routinely finding and consuming nutritional supplement products. This problem is solved by Appellant's invention.

THE LAW DOES NOT MANDATE RDA INFORMATION IN LABELING A DRUG NOT INTENDED TO SUPPLEMENT NUTRITION

The Examiner states that putting information about RDA of vitamin C in the package insert is mandated by law, (pages 2 and 3 of the Advisory action dated May 6, 2004). But, information about RDA is not mandated by law for labeling a product, that is not a food or a dietary supplement product. Also, it is not obvious over the applied prior art to put information about RDA on package inserts for products based on SS Pharmaceutical, Tsunoda, and Yeh et al.

Recommended Daily Allowance (RDA) is not disclosed in drug labeling law

21 CFR 201.57 and 21 CFR 201.60-66. So, it is not mandated by drug labeling law to put information about RDA of vitamin C in a package insert. Food and dietary supplement labeling laws do not mandate putting information about RDA on a label or package insert for products that are not food or dietary supplement products. SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose a food or a dietary supplement product, and, they are not properly combined with Krause, as discussed above. They do not disclose food or dietary supplement products, because they do not disclose protein, fat, carbohydrate, and energy value, or any intention to supplement nutrition, as see Krause page 279, right column, first paragraph; 21 CFR 101.36; 21 CFR 101.9 (c), and EXHIBIT E of the April 1, 2004 Amendment. Thus, it is not mandated by labeling laws, to put information about RDA of antioxidant and/or synergistic vitamin C on a label or package insert of products based on the disclosures of SS Pharmaceutical, Tsunoda, and Yeh et al.

Yeh et al teach away from indicating information about RDA by disclosing that a vitamin can be replaced by another vitamin, by portion of a vitamin or by a compound that is not a vitamin, as discussed above. Each vitamin is essential to good health regardless of how much of anything else is consumed, Lieberman and Bruning, The Real Vitamin and Mineral Book, 1997, page 17: EXHIBIT A of the Supplemental Remarks filed May 19, 2004. Thus, for the function of supplementing nutrition and the purpose of RDA a vitamin cannot be replaced by another vitamin, a portion of a vitamin or a compound that is not a vitamin.

Neither an amount, an RDA, or a percent daily value of a vitamin or a mineral nor any intention of supplementing nutrition is disclosed by SS Pharmaceutical, Tsunoda, or Yeh et al. And, they are not properly combined with Krause, as discussed above. By not disclosing any amount, RDA or a percent daily value for any antioxidant vitamin SS Pharmaceutical, Tsunoda, and Yeh et al teach away from the function and indication of RDA, supplementing nutrition and the invention. Furthermore, by disclosing antioxidants to reduce pain, inflammation and/or periodontal disease, rather than for supplementing nutrition, SS Pharmaceutical, Tsunoda, and Yeh et al teach away from the function of supplementing nutrition and its indication. So, no information about amount, RDA, percent daily value or

supplementing nutrition would be provided on a label or package insert for antioxidant and/or synergistic ascorbic acid as part of a pain reliever product based on SS Pharmaceutical, Tsunoda, and Yeh et al. And, the consumers of products based on them would have to consume separate nutritional supplement products to know that they are consuming sufficient vitamins and/or minerals.

Indicating RDA is taught away from, and unintended for synergistic and/or antioxidant vitamins of products based on SS Pharmaceutical, Tsunoda, and Yeh et al, as discussed above. Unintended functions, which are taught away from, are not obvious to indicate in a product's package insert or its label. So, it is not obvious over the prior art or mandated by drug, food or dietary supplement labeling laws, to put information about RDA of vitamin C on a label or package insert of products based on the disclosures of SS Pharmaceutical, Tsunoda, and Yeh et al. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

NUTRITIONAL LABELING IS NOT MANDATED FOR DRUGS, WHICH ARE NOT PROVIDED FOR SUPPLEMENTING NUTRITION

The Examiner states that the indications that provide the superior results are expected because the law requires them (page 8 of the Final Rejection). But, the law does not require indications indicating supplementing nutrition and/or percent daily value for products that are not intended to supplement nutrition. And, if they were required, then commercial pain reliever products containing vitamins and/or minerals would have these indications and the results. Since these products do not have these indications or their results, they are not required by law.

Food and dietary supplement labeling laws do not mandate labeling of products, which are not food or dietary supplement products, as discussed above (Krause and 21 CFR 101.9 and 101.36 and EXHIBIT F.1 of the April 1, 2004 Amendment). SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose a food or a dietary supplement product and teach away from indicating supplementing nutrition, as discussed above. So, food and dietary supplement labeling laws are not mandatory for products based on SS Pharmaceutical, Tsunoda, and Yeh et al,

which are not intended for supplementing nutrition. They are improperly combined with Krause, as discussed above. Thus, indications such as indicating supplementing nutrition and/or percent daily value are not required by food and dietary supplement labeling laws for products, based on SS Pharmaceutical, Tsunoda, and Yeh et al, which are not intended for supplementing nutrition.

The indications indicating supplementing nutrition and/or percent daily value are not required by drug labeling law, because it does not disclose them, 21 CFR 201.57 and 201.60 -.66. Neither over-the-counter (OTC) drug labeling law, nor prescription drug labeling law, discloses percent daily value or supplementing nutrition 21 CFR 201.57 and 201.60 to 201.66. Also, drug labeling law does not refer to nutrition labeling. Thus, indications indicating supplementing nutrition and/or percent daily value are not required by drug labeling law, because it does not disclose them.

Use of Appellant's invention results in superior savings of half of the number of unit dose compositions and half of the number of containers, while maintaining the same discomfort relief and the same ability to self regulate consumption of nutritional supplements as in the prior art, as discussed above. Additionally, Appellant's invention provides the superior result of the consumer regularly consuming a nutritional supplement, without having to routinely remember to find and consume the nutritional supplement product. By, contrast when using prior art products, the consumer must regularly remember to find and consume a nutritional supplement from a distinctively labeled separate container. So, patentability is shown beyond the requirements of the statute, Demaco Corp v F Von Langsdorff Licensing Ltd. 7 USPQ2d 1222 (Fed. Cir 1988).

If the indications that provide the superior results were required by law, then prior commercial pain reliever products that contain vitamins and/or minerals would have indications indicating supplementing nutrition and/or percent daily value. But, they do not have these indications. So, consumers of prior commercial pain reliever products, need to find and consume separate distinctively labeled nutritional supplements, to know that they are consuming sufficient amounts of nutritional supplements. Thus, prior commercial pain reliever products containing vitamins

and/or minerals do not have indications indicating supplementing nutrition and/or percent daily value, because they are not intended to supplement nutrition, and the indications are not required.

For example, prior commercial pain reliever packaging indicates that salts and oxides of minerals are included, as buffering agents and/or inert or inactive ingredients (Advil, Motrin, Aleve, Tylenol, Excedrin or Bufferin: Exhibits A-G of the Amendment filed March 1, 2004). But, no indications are provided indicating names, amounts or percent daily values of any minerals. Thus, supplementing nutrition is not intended by these prior commercial pain reliever products. So, the law does not require them to have indications indicating supplementing nutrition. And, consumers do not know the amount of each mineral or the percent daily value of the undisclosed amount of each mineral consumed. Thus, they need to consume separate distinctively labeled nutritional supplement products, to know that they are consuming sufficient vitamins and/or minerals.

IT IS NOT OBVIOUS TO PUT INFORMATION ON A LABEL REGARDING UNINTENDED USES OF THE PRODUCT

The Examiner states that just because pain reliever products, which are not nutritional products, do not include nutrition information, does not obviate putting the information on the label, (Advisory Action dated March 24, 2004, paragraph 5 continuation, at "Secondly"). But, just because a prior product does not include a feature, does not obviate including it, is not the standard for obviousness. Rather, the standard with which obviousness is determined, is a reasonable expectation of success. Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986) and MPEP 2141. And, success cannot be reasonably expected in indicating supplementing nutrition on the label of a product, which is based on disclosures that are not intended to supplement nutrition, and that teach away from supplementing nutrition.

The court has stated that a teaching or suggestion to make the claimed combination and a reasonable expectation of success must both be found in the prior art, not in Appellant's disclosure In re Vaeck 947 F 2d 488, 20 USPQ2d 1438 (Fed. Cir 1991). SS Pharmaceutical, Tsunoda, and Yeh et al teach away from

indicating supplementing nutrition, and are not properly combined with Krause, as discussed above. Thus, the combination of references of the rejection does not have a teaching to make the claimed combination, or a reasonable expectation of success.

New and additional features of Appellant's invention include: indications indicating supplementing nutrition; a percent of a daily value and/or instructions for supplementing nutrition, each in a method of indication for a discomfort reliever in an enclosure. These features are not disclosed by the applied prior art. All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. And, success cannot be reasonably expected in indicating supplementing nutrition on the label of a product based on disclosures that are not properly combined, are not intended for supplementing nutrition, and teach away from supplementing nutrition, as discussed above. So, the rejection of Appellant's invention does not have a reasonable expectation of success: the standard with which obviousness is determined, Hodosh. And, the rejection does not meaningfully consider all of the limitations of the claims, Perkin – Elmer Corp. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

USE IN SUPPLEMENTING NUTRITION IS NOT MANDATED BY 21 CFR 201.57

The Examiner states that indication for use is mandated by 21 CFR 201.57, pages 4 and 5 of the Final Rejection. But, 21 CFR 201.57 does not mandate indication for use in supplementing nutrition. And, use of vitamin C to reduce pain and/or inflammation is neither a solution for the consumer's problems, nor an FDA approved use.

Drug labeling law does not disclose indicating use in supplementing nutrition, 21 CFR 201.57 and 21 CFR 201.60-66. So, no indication for use in supplementing nutrition is mandated by drug labeling law. Accordingly, drug labeling law does not mandate including indications for use in supplementing nutrition in labeling products based on SS Pharmaceutical, Tsunoda, and Yeh et al.

Food and dietary supplement labeling laws do not mandate including

indications for labeling products which are not food or nutritional supplements, 21 CFR 101.9 and 21 CFR 101.36. SS Pharmaceutical, Tsunoda, and Yeh et al, do not disclose a food or a dietary supplement. And, they are not properly combined with Krause, as discussed above. They do not disclose food, because they do not disclose protein, fat, carbohydrate, and energy value, as see Krause page 279, right column, first paragraph; 21 CFR 101.9 (c). And, they do not disclose dietary supplements, because they do not disclose any intention to supplement nutrition (EXHIBIT E of the April 1, 2004 Amendment). Accordingly, food or dietary supplement labeling laws do not mandate including indications for use in supplementing nutrition, in labeling products based on the disclosures of SS Pharmaceutical, Tsunoda, and Yeh et al.

SS Pharmaceutical, Tsunoda, or Yeh et al do not disclose any intention of use for supplementing nutrition, as discussed above. Rather, they teach away from indicating supplementing nutrition, and they are not properly combined with Krause, as discussed above. So, indications for use in supplementing nutrition are not obvious over the applied prior art, In re Sernaker. Thus, it would not be obvious over the applied prior art to include indications for use in supplementing nutrition in labeling products based on SS Pharmaceutical, Tsunoda, and Yeh et al. Accordingly, it is not mandated by drug, food or dietary supplement labeling laws, or obvious over the prior art, to include indications for use in supplementing nutrition in labeling products based on the disclosures of SS Pharmaceutical, Tsunoda, and Yeh et al.

Vitamin C is not disclosed as being clinically effective in reducing pain or inflammation. All indications must be supported by substantial evidence based on adequate and well controlled studies 21 CFR 201.57(c)(2) and 21 CFR 314.126(b). But, even if vitamin C were approved for use in reducing pain or inflammation, labeling for this use does not solve the consumer's problem of needing to know the percent daily values of vitamins and/or minerals consumed. This problem is solved by Appellant's invention.

It is noted that ibuprofen pain reliever labeling is mandated by 21 CFR 201.57. And, this mandate is complied with in labeling commercial pain relievers,

Exhibits A and B of the Amendment dated March 1, 2004. But, this does not solve the consumer's problem of not knowing the names and percent daily values of vitamins and minerals consumed. This problem is solved by Appellant's invention.

APPELLANT DOES NOT CLAIM A CHEMICAL COMPOSITION

The Examiner states that the identical chemical composition cannot have mutually exclusive properties, and vitamin C functions as nutritional supplement regardless of whether the prior art teaches so, (pages 9 and 10 of the Final Rejection). The Examiner states that the claimed composition functions the same regardless of what is printed on the package and/or such function being taught by the prior art (Advisory Action dated March 24, 2004, paragraph 5 continuation). But, Appellant does not claim a composition. And, a product is not a nutritional supplement product unless it is intended to supplement nutrition, as discussed above. Also, SS Pharmaceutical, Tsunoda, and Yeh et al teach away from the function of supplementing nutrition. Additionally, identical chemical compositions functioning the same do not solve the problems of the prior art of having to regularly remember to find and consume nutritional supplements from separate distinctively labeled containers. These problems are solved by Appellant's invention.

Dietary supplements are products intended to supplement the diet (EXHIBIT E of the April 1, 2004 Amendment). So, a product must be intended to supplement nutrition to be indicated as being a nutritional supplement. Thus, the unintended possibility of chemical compositions and their functions and properties being identical does not lead one to label products as dietary supplements.

SS Pharmaceutical, Tsunoda, and/or Yeh et al do not disclose percent daily values or the function of supplementing nutrition. So, they do not disclose dietary supplement products. They teach away from the function and indication of supplementing nutrition by not disclosing any amount or percent daily value for any antioxidant vitamin. And, they teach away from indicating supplementing nutrition by disclosing vitamin C as a synergist and/or an antioxidant to reduce pain and/or inflammation, rather than for supplementing nutrition. They are not properly combined with Krause. Thus, it would not be obvious to indicate the function of supplementing nutrition in labeling and/or by printing on the packaging for a product

based on them. And, the consumer does not know the amounts or percent daily values of any antioxidant vitamins consumed in products based on SS Pharmaceutical, Tsunoda, and Yeh et al. So, identical chemical compositions functioning the same do not solve the problems of the prior art. Appellant's invention provides a method of providing a unit dose of a discomfort reliever in an enclosure having indications indicating supplementing nutrition. This enables consumers to self regulate their consumption of vitamins and minerals.

Yeh et al teach away from the function of supplementing nutrition and its indication by disclosing that a vitamin can be replaced by another vitamin, by portion of a vitamin or by a compound that is not a vitamin, as discussed above, column 2, lines 48-52. Even though one antioxidant may have the same antioxidant function as another. Different antioxidants do not have the same function in supplementing nutrition. Each vitamin is essential to good health regardless of how much of anything else is consumed, Lieberman and Bruning, The Real Vitamin and Mineral Book, 1997, page 17: EXHIBIT A of the Supplemental Remarks filed May 19, 2004. Thus, the nutrition supplementing function of a vitamin cannot be replaced by another vitamin, a portion of a vitamin or a compound that is not a vitamin. So, products based on Yeh et al are not nutritional supplement products. And, any function of supplementing nutrition would be unintended in products containing antioxidant and/or synergistic ascorbic acid based on Yeh et al. Thus, identical chemical compositions functioning the same do not solve the problems of the prior art of having to regularly remember to find and consume nutritional supplements from separate distinctively labeled containers. These problems are solved by Appellant's invention.

The same amount of nutrition supplementing function is not provided by the same amounts of different antioxidant compounds. Yeh et al discloses ascorbic acid and its salts as antioxidants, (column 2, lines 48-52). But, equal amounts of ascorbic acid and magnesium ascorbate do not have the same percent daily value, (Lieberman and Bruning, The Real Vitamin and Mineral Book, 1997, page 126-127 APPENDIX B). So, even if their amounts were indicated, the consumer does not know when a sufficient amount of vitamin is being consumed for supplementing

nutrition. Thus, identical chemical compositions functioning the same do not solve the problems of the prior art of having to regularly remember to find and consume nutritional supplements from separate distinctively labeled containers. These problems are solved by Appellant's invention.

The possibility of identical chemical compositions and their functions and/or properties do not solve the consumer's problems. For example, a prior commercial pain reliever is buffered with calcium carbonate and sold under the name Bufferin, (Exhibit G of the Amendment filed March 1, 2004). Its label does not have any indication indicating supplementing nutrition, the amount of calcium, or the percent daily value of the undisclosed amount of calcium. And, the consumer does not know whether or not Bufferin is effectively identical or substantially different nutritionally, compared to the new commercial pain reliever with thirty percent daily value of calcium introduced by Bayer in 2002 (Bayer Consumer Care and Tony Raines Race for Women's Health in New Hampshire, page 1 first paragraph- EXHIBITS A and B of the April 1, 2004 Amendment). So, consumers of this prior commercial pain reliever, must regularly remember to find and consume nutritional supplements from separate distinctively labeled containers, to know that they are consuming sufficient vitamins and/or minerals. Thus, the possibility of identical chemical compositions and their functions and/or properties does not solve these problems. These problems are solved by Appellant's invention.

Also, regardless of unintended safe functions of their chemical compositions, both nutritional supplement products and discomfort reliever products are defined by their intended purpose, which then controls what is mandated to be printed on their packaging. Drugs are defined by their intended use, EXHIBIT D, of the April 1, 2004 Amendment. A dietary supplement is a product intended to supplement the diet that contains a vitamin or mineral EXHIBIT E of the April 1, 2004 Amendment. Any function of supplementing of nutrition is taught away from, and unintended for synergistic and/or antioxidant vitamins of SS Pharmaceutical, Tsunoda, and Yeh et al, as discussed above. Functions of synergistic and/or antioxidant vitamins, which are unintended and taught away from, are not obvious to indicate in printing a pain reliever product label. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48,

50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

The Examiner states that the ultimate function of the instant composition relies on the active ingredients: ibuprofen and vitamin C (page 8 of the Final Rejection). But, Appellant does not claim a composition. Appellant claims a method of indicating supplementing nutrition. A product must be intended to supplement nutrition to be indicated as a dietary supplement, as discussed above. SS Pharmaceutical, Tsunoda, and Yeh et al teach away from the function and indication of supplementing nutrition.

Dietary supplements are products intended to supplement the diet (EXHIBIT E of the April 1, 2004 Amendment). So, more then function is needed for a product containing a vitamin or mineral to be a dietary supplement product. Thus, all products containing a vitamin and/or mineral are not dietary supplement products, just because an unintended function relies on an ingredient. Also, an unintended function of a composition does not solve the consumer's problem of needing to know the percent daily values of the vitamins and minerals consumed. Appellant's invention provides a method of providing a unit dose of a discomfort reliever in an enclosure having indications indicating supplementing nutrition. This enables consumers to self regulate their consumption of vitamins and minerals.

Yeh et al teach away from the function and indication of supplementing nutrition, by not disclosing the vitamin function of ascorbic acid, its vitamin name, its amount or its percent daily value. They teach away from the function and indication of supplementing nutrition, by disclosing only one (alpha-tocopherol) of the eight compounds that make up vitamin E. And, they teach away from the function and indication of supplementing nutrition, by teaching that a vitamin can function the same as another vitamin, a small fraction of a vitamin, or a compound that is not a vitamin, (column 2, lines 48-52). Also, they teach away from the function and indication of supplementing nutrition by teaching reduction of inflammation and/or periodontal disease, rather supplementing nutrition. These portions of the reference teach away from the function and indication of supplementing nutrition and the claimed invention, and must be considered, Bausch & Lomb Inc v Barnes-

Hind/Hydrocurve, Inc, 796 F2d 443; 230 USPQ 416 (CAFC 1986).

By not disclosing any amount or a percent daily value for any antioxidant vitamin SS Pharmaceutical, Tsunoda, and Yeh et al teach away from the function and indication of supplementing nutrition and the invention. They disclose reducing pain and/or inflammation as functions of synergist and/or antioxidant vitamin C (ascorbic acid). They do not disclose the function of supplementing nutrition. So, they do not disclose dietary supplement products. And, they do not disclose a product that would enable the consumer to know the amount or percent daily value of any vitamin or mineral. They are not properly combined with Krause, and teach away from indicating supplementing nutrition, as discussed above. And, indicating vitamin C as supplementing nutrition for products based on them would not be obvious, since any nutrition supplementing function of synergistic and/or antioxidant vitamin C is unintended, and taught away from. Their teaching away from indicating the function of supplementing nutrition, and the invention, supports a conclusion of nonobviousness, Dow Chemical Co v US,18 USPQ2d 1657, 1662 (US Claims Ct, 1990). Portions of a reference teaching away from the claimed invention must be considered, Bausch & Lomb Inc. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

Consumers of prior commercial pain reliever products containing vitamins and/or minerals cannot regulate their consumption of those vitamins and/or minerals, because their names, amounts and percent daily values are not indicated in their labeling. So, for them to know that they are consuming nutritionally sufficient amounts of vitamins and minerals, they need to consume separate distinctively labeled nutritional supplements too.

For example, prior commercial pain reliever products include iron, calcium and magnesium in the form of salts and oxides of minerals as buffering agents and/or an inert or inactive ingredients: Advil, Motrin, Aleve, Tylenol, Excedrin and Bufferin. (Exhibits A-G of the Amendment filed March 1, 2004). Salts and/or oxides are sometimes used to provide the minerals: calcium, iron and magnesium (Lieberman and Bruning, The Real Vitamin and Mineral Book, 1997, pages 138, 146

and 157: EXHIBIT A of the Supplemental Remarks filed May 19, 2004). But, they do not indicate the mineral names, mineral amounts, percent daily values of minerals or recommended daily allowances of any minerals. Thus, salts and oxides of minerals, as inert ingredients and/or buffering agents are not intended for supplementing nutrition. And, consumers do not know the amounts of the minerals or their percent daily values. So, unintended functions of buffering agents and/or inert or inactive ingredients do not solve these problems. These problems are solved by Appellant's invention.

APPELLANT DOES NOT CLAIM A DEVICE

The Examiner states that the indications are not functionally related to the composition, and that printed material does not patentably distinguish over the prior art, citing Application of Miller 164 USPQ 46 (CCPA 1969) and In re Gulack 703 F2d 1381, 217 USPQ 401 (CAFC, 1983), (pages 8-9 of the Final Rejection). But, Appellant does not claim a device, as was claimed in Application of Miller and In re Gulack. Appellant claims a method of indication for a unit dose of discomfort reliever in an enclosure having indications indicating supplementing nutrition. Neither SS Pharmaceutical, Tsunoda, Yeh et al nor Krause disclose these features. And they are not properly combined with Krause, as discussed above. So, the rejection is improper because of the absence from the applied references of explicit requirements of the claims, In re Evanega. Accordingly, the rejection of Claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is improper and erroneous.

The Examiner notes that the consumer can take the medication without having the written instructions at hand, at page 5 of the May 6, 2004 Advisory action citing Application of Miller and In re Gulack. But, Appellant does not claim a device as was claimed in Application of Miller and In re Gulack. And, Appellant does not claim a composition, as discussed above. A consumer may refer to indications indicating supplementing nutrition before and/or after removing a medication from the enclosure in Appellant's method of indication. Appellant claims a method of indication for a unit dose of discomfort reliever and nutritional supplement in an

enclosure having indications indicating supplementing nutrition. Neither SS Pharmaceutical, Tsunoda, Yeh et al nor Krause discloses these features. And they are not properly combined, as discussed above. Also, SS Pharmaceutical, Tsunoda, and Yeh et al teach away from supplementing nutrition and the invention claimed by Appellant, as discussed above. So, the rejection is improper because of the absence from the applied references of explicit requirements of the claims, In re Evanega. And, it is improper because SS Pharmaceutical, Tsunoda, and Yeh et al teach away the invention, Bausch & Lomb Inc v Barnes-Hind/Hydrocurve, Inc, 796 F2d 443; 230 USPQ 416 (CAFC 1986). Accordingly, the rejection of Claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is improper and erroneous.

SUMMARY

SS Pharmaceutical, Tsunoda, and Yeh et al are not properly combined with Krause, because nothing is taught in them to suggest their combination. The combination of references is improper because it does not meaningfully consider all of the limitations of the claims, and is based on forbidden hindsight. SS Pharmaceutical, Yeh et al and Tsunoda teach away from indicating supplementing nutrition, percent daily value and Appellant's invention. So, the combination of references does not have a reasonable expectation of success.

Appellant's invention omits half of the number of unit dose compositions and half of the number of containers required by the prior art with retention of all of their functions. These are data of superior results, and indicia of unobviousness, provided while maintaining the same discomfort relief and the same ability to self regulate consumption of nutritional supplements as in the prior art. So, patentability is shown beyond the requirements of the statute.

Appellant's invention is not obvious over the applied prior art references. It is not mandated by law. It eliminates unit dose compositions and containers. And, it enables consumers to self regulate their consumption of vitamins and/or minerals while relieving a discomfort. Consumers regularly consume nutritional supplements, without having to routinely remember to find and consume them, by

using Appellant's invention.

Reversal of the final rejection and allowance of the claims is respectfully requested.

Respectfully submitted,

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July 7, 2004

APPENDIX A

26. A method of indication for a unit dose of an orally consumable material for relief of discomfort and supplementing nutrition, comprising:

enclosing a unit dose of orally consumable material in an enclosure having indications, said unit dose comprising a predetermined amount of discomfort reliever, and a predetermined amount of at least one nutritional supplement selected from the group consisting of vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin E, vitamin K, folic acid, niacin, biotin, beta-carotene, pantothenic acid, calcium, chlorine, chromium, copper, iodine, iron, manganese, molybdenum, phosphorus, potassium, and zinc,

said indications indicating said amount of said discomfort reliever in said unit dose,

said indications indicating said amount of said nutritional supplement in said unit dose,

said indications indicating a percent of a daily value for said nutritional supplement in said unit dose, and

said indications indicating that consumption of said discomfort reliever of said unit dose provides relief for at least one discomfort selected from the group consisting of aches, pain, fever, running nose, sneezing, itching of nose, itching of throat, itchy watering eyes due to upper respiratory allergy, insomnia, sleepiness, fatigue and drowsiness.

27. The method of claim 26 wherein said nutritional supplement is vitamin C and said discomfort reliever is ibuprofen.

28. The method of claim 26 wherein said nutritional supplement comprises at least 50 mg of vitamin C and said discomfort reliever comprises at least 50 mg of ibuprofen.

29. The method of claim 26 wherein said indications indicate temporary relief for at least two discomforts selected from the group consisting of minor pain, headache, toothache, backache, muscular aches, fever, running nose, sneezing, itching of nose, itching of throat, itchy watering eyes due to upper respiratory allergy, sleepiness, fatigue and drowsiness.

30. The method of claim 26 wherein said indications indicate temporary relief for a discomfort selected from the group consisting of headache, toothache, backache, muscular aches, minor pain of arthritis, fever, running nose, sneezing, itching of nose, itching of throat, itchy watering eyes due to upper respiratory allergy, sleepiness, fatigue and drowsiness.

33. The method of claim 26 wherein said discomfort is pain, and said discomfort reliever is selected from the group consisting of ibuprofen, naproxen, caffeine, acetaminophen and aspirin, said nutritional supplement is vitamin C, calcium or iron and said percent of a daily value is between one and fifty percent of a daily value.

34. The method of claim 26 wherein said unit dose is formed into a pill, tablet or capsule.

35. The method of claim 26 wherein said said discomfort reliever is selected from the group consisting of ibuprofen, naproxen, caffeine, aspirin, and acetaminophen, and said nutritional supplement is selected from the group consisting of vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin E, vitamin K, calcium, chlorine,

chromium, copper, iodine, iron, manganese, molybdenum, phosphorus, potassium, and zinc.

37. The method of claim 26 wherein said discomfort is headache.

38. A method of indication for a unit dose of an orally consumable material for relief of discomfort and supplementing nutrition, comprising:

enclosing a unit dose of orally consumable material, in an enclosure having indications, said unit dose comprising a predetermined amount of discomfort reliever selected from the group consisting of ibuprofen, naproxen, caffeine, and acetaminophen, and a predetermined amount of at least one nutritional supplement selected from the group consisting of vitamin, and mineral,

said indications indicating said amount of said discomfort reliever in said unit dose,

said indications indicating said amount of said nutritional supplement in said unit dose, said indications indicating a percent of a daily value for said nutritional supplement in said unit dose, and said indications indicating that consumption of said discomfort reliever of said unit dose provides relief for at least one discomfort selected from the group consisting of aches, pain, fever, running nose, sneezing, itching of nose, itching of throat, itchy watering eyes due to upper respiratory allergy, sleepiness, fatigue and drowsiness.

39. The method of claim 38 wherein said unit does consists essentially of said nutritional supplement and said discomfort reliever, and said nutritional supplement is vitamin C and said discomfort reliever is ibuprofen.

40. The method of claim 38 wherein said indications indicate that consumption of

said unit dose provides temporary relief for at least two discomforts selected from the group consisting of minor pain, headache, toothache, backache, muscular aches, fever, running nose, sneezing, itching of nose, itching of throat, itchy watering eyes due to upper respiratory allergy, sleepiness, fatigue and drowsiness.

41. The method of claim 38 wherein said nutritional supplement is vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin E, vitamin K, calcium, chromium, copper, iron, manganese, molybdenum, phosphorus, potassium or zinc.

42. The method of claim 38 wherein said indications comprise printed indications, and said printed indications are supported by said enclosure and said unit dose is formed into a pill, tablet or capsule.

43. The method of claim 38 wherein said unit dose of an orally consumable material comprises at least 50 mg of said nutritional supplement and at least 50 mg of said discomfort reliever.

44. A method of indication for a unit dose of an orally consumable material for relief of discomfort and for supplementing nutrition with nutritional supplement, comprising:

enclosing a unit dose of orally consumable material in an enclosure having indications, said unit dose comprising a predetermined amount of at least 50 mg of discomfort reliever, and a predetermined nutritionally effective amount of nutritional supplement, and said nutritional supplement is vitamin C, calcium, iron or iodine,

said indications indicating said amount of said discomfort reliever in said unit dose,

said indications indicating said amount of said nutritional supplement in said

unit dose, said indications indicating a percent of a daily value for said nutritional supplement in said unit dose, and said indications indicating that consumption of said discomfort reliever of said unit dose provides relief for at least one discomfort selected from the group consisting of aches, pain, fever, running nose, sneezing, itching of nose, itching of throat, itchy watering eyes due to upper respiratory allergy, insomnia, sleepiness, fatigue and drowsiness.

45. The method of claim 44 wherein said nutritional supplement is vitamin C and said discomfort reliever is ibuprofen, said unit dose has a form selected from the group consisting of pill, tablet, and capsule.

46. The method of claim 26 wherein said discomfort is sleepiness, fatigue or drowsiness.

48. A method of indication for a unit dose of an orally consumable material for relief of discomfort and supplementing nutrition, comprising:

enclosing a unit dose of orally consumable material in an enclosure having indications, said unit dose comprising a predetermined amount of discomfort reliever, and a predetermined amount of at least one nutritional supplement selected from the group consisting of vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin E, vitamin K, folic acid, niacin, biotin, beta-carotene, pantothenic acid, calcium, chlorine, chromium, copper, iodine, iron, manganese, molybdenum, phosphorus, potassium, and zinc,

said indications indicating said amount of said discomfort reliever in said unit dose, said indications indicating said amount of said nutritional supplement in said unit dose,

said indications indicating said nutritional supplement for supplementing nutrition, and

said indications indicating said discomfort reliever as being for relief of at least one discomfort selected from the group consisting of aches, and pain, fever, running nose, sneezing, itching of nose, itching of throat, itchy watering eyes due to upper respiratory allergy, insomnia, sleepiness, fatigue and drowsiness.

49. The method of claim 48 wherein said discomfort reliever is an antihistamine.

50. The method of claim 48 wherein said unit dose consists essentially of said discomfort reliever and said nutritional supplement, and said nutritional supplement consists essentially of vitamin C, calcium or iron.

51. The method of claim 48 wherein said indications indicate that consumption of said unit dose is for women.

52. The method of claim 48 wherein said indications indicate a percent of a daily value for said nutritional supplement in said unit dose.

53. The method of claim 48 wherein said unit dose comprises from about 50 to about 300 mg of a discomfort reliever selected from the group consisting of ibuprofen, naproxen, caffeine, aspirin and acetaminophen, and from about 50 to about 1000 mg said nutritional supplement, and said nutritional supplement consists essentially of vitamin C, potassium, phosphorous or calcium.

54. The method of claim 52 wherein said discomfort reliever is ibuprofen, caffeine or aspirin, and said nutritional supplement is vitamin C or calcium.

55. The method of claim 48 wherein said discomfort reliever is buffered aspirin.

57. The method of claim 48 wherein said unit dose comprises nutritionally effective

amounts of at least two nutritional supplements selected from said group, at least one of said nutritional supplements is a vitamin, and at least one of said nutritional supplements is a mineral.

58. The method of claim 48 wherein said unit dose comprises at least three nutritional supplements selected from said group.

59. The method of claim 48 wherein said amount of said discomfort reliever is a pharmaceutically effective amount and said amount of said nutritional supplement is a nutritionally effective amount.

60. The method of claim 48 wherein said discomfort is insomnia, sleepiness, fatigue or drowsiness.

61. The method of claim 48 wherein said discomfort reliever is indicated as being an analgesic.

62. The method of claim 48 wherein said discomfort reliever comprises caffeine, acetaminophen or aspirin.

63. The method of claim 48 wherein said indications indicate a percent of a daily amount for said nutritional supplement in said unit dose, said nutritional supplement is calcium and said discomfort reliever is aspirin.

64. The method of claim 48 wherein said indications are for a consumer of said unit dose.

65. The method of claim 48 wherein said amount of said nutritional supplement in said unit dose is from about 50 to about 1000 mg.

66. The method of claim 65 wherein said amount of discomfort reliever in said unit dose is from about 50 to about 300 mg.

67. A method of indication for a unit dose of an orally consumable material for relief of discomfort and for supplementing nutrition, comprising:

enclosing a unit dose of orally consumable material in an enclosure having indications, said unit dose comprising a predetermined amount of discomfort reliever, and a predetermined amount of at least one nutritional supplement, said nutritional supplement being selected from the group consisting of vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin E, vitamin K, folic acid, niacin, biotin, beta-carotene, pantothenic acid, boron, calcium, chlorine, copper, iodine, iron, manganese, molybdenum, nickel, phosphorus, potassium, selenium, tin and zinc,

said indications indicating said amount of said discomfort reliever in said unit dose, said indications indicating said amount of said nutritional supplement in said unit dose,

said indications indicating supplementing nutrition and

said indications indicating said discomfort reliever in said unit dose as being for relief of at least one discomfort selected from the group consisting of aches, pain, fever, running nose, sneezing, itching of nose, itching of throat, itchy watering eyes due to upper respiratory allergy, insomnia, sleepiness, fatigue and drowsiness.

68. The method of claim 67 wherein said indications indicate a percent of a daily value for said nutritional supplement in said unit dose.

69. The method of claim 67 wherein said unit dose comprises from about 50 to about 300 mg of said discomfort reliever, said unit dose comprises from about 50 to about 1000 mg of said nutritional supplement, and said nutritional supplement is vitamin C or calcium.

70. The method of claim 67 wherein said nutritional supplement is calcium and said discomfort reliever comprises aspirin.

71 The method of claim 67 wherein said unit dose comprises a pharmaceutically effective amount of said discomfort reliever and nutritionally effective amount of said nutritional supplement.

72. The method of claim 67 wherein said discomfort reliever is selected from the group consisting of ibuprofen, naproxen, caffeine, aspirin and acetaminophen.

73. The method of claim 67 wherein said unit dose consists essentially of said discomfort reliever and said nutritional supplement.

74. The method of claim 67 wherein said discomfort is insomnia, sleepiness, fatigue or drowsiness.

76. The method of claim 67 wherein said indications indicate said discomfort reliever in said unit dose as being primarily for relief of said discomfort.

77. The method of claim 67 wherein said indications are for said consumer, said discomfort reliever is ibuprofen, naproxen, caffeine, aspirin or acetaminophen, said nutritional supplement is vitamin C, calcium, iodine or iron.

78. The method of claim 77 wherein said indications indicate said unit dose comprises from about 50 to about 300 mg of said discomfort reliever, and said unit dose comprises from about 50 to about 1000 mg of said nutritional supplement.

79. The method of claim 67 wherein said indications indicate instructions for consuming the unit dose for supplementing nutrition.

80. The method of claim 67 wherein said unit dose consists essentially of a pharmaceutically effective amount of said discomfort reliever and nutritionally

effective amount of said nutritional supplement.

81. The method of claim 67 wherein said unit dose comprises nutritionally effective amounts of at least three nutritional supplements selected from said group.

82. A method of indication for a unit dose of an orally consumable material for relief of discomfort and for supplementing nutrition, comprising:

enclosing a unit dose of orally consumable material in an enclosure having indications, said unit dose comprising a predetermined amount of discomfort reliever, and a predetermined amount of at least one nutritional supplement, said nutritional supplement being selected from the group consisting of vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin E, vitamin K, folic acid, niacin, biotin, beta-carotene, pantothenic acid, boron, calcium, chlorine, copper, iodine, iron, manganese, molybdenum, nickel, phosphorus, potassium, selenium, tin and zinc,

said indications indicating said amount of said discomfort reliever in said unit dose,

said indications indicating a percent daily value for said nutritional supplement and

said indications indicating said discomfort reliever in said unit dose as being for relief of at least one discomfort selected from the group consisting of aches, pain, fever, running nose, sneezing, itching of nose, itching of throat, itchy watering eyes due to upper respiratory allergy, insomnia, sleepiness, fatigue and drowsiness.

83. The method of claim 82 wherein said unit does consists essentially of a pharmaceutically effective amount of said discomfort reliever and a nutritionally effective amount of said nutritional supplement, said discomfort reliever is ibuprofen,

naproxen, caffeine, aspirin or acetaminophen, said nutritional supplement consists essentially of vitamin C, calcium, iodine or iron.

85. The method of claim 82 wherein said unit does consists essentially of a pharmaceutically effective amount of said discomfort reliever and a nutritionally effective amount of said nutritional supplement, said discomfort reliever is ibuprofen, naproxen, caffeine, aspirin or acetaminophen, said nutritional supplement is a mineral.

86. The method of claim 85 wherein said percent of a daily value is between about one and about fifty percent.

87. The method of claim 82 wherein said nutritional supplement is calcium or iron, said discomfort reliever is ibuprofen or aspirin and said discomfort is aches or pain.

88. The method of claim 82 wherein said nutritional supplement is calcium, said discomfort reliever is aspirin and said discomfort is pain.

89. The method of claim 82 wherein said unit dose comprises nutritionally effective amounts of at least two nutritional supplements selected from said group, at least one of said nutritional supplements is a vitamin, and at least one of said nutritional supplements is a mineral.

90. The method of claim 82 wherein said unit dose comprises nutritionally effective amounts of at least three nutritional supplements selected from said group.

91. A method of indication for a unit dose of an orally consumable material for relief of discomfort and for supplementing nutrition, comprising:

enclosing a unit dose of orally consumable material in an enclosure having indications, said unit dose consisting essentially of a predetermined

pharmaceutically effective amount of discomfort reliever, and a predetermined nutritionally effective amount of nutritional supplement, said nutritional supplement consisting essentially of vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin E, vitamin K, folic acid, niacin, biotin, beta-carotene, pantothenic acid, boron, calcium, chlorine, copper, iodine, iron, manganese, molybdenum, nickel, phosphorus, potassium, selenium, tin or zinc,

said indications indicating said amount of said discomfort reliever in said unit dose,

said indications indicating a percent daily value for said nutritional supplement and

said indications indicating said discomfort reliever in said unit dose as being for relief of at least one discomfort selected from the group consisting of aches, pain, fever, running nose, sneezing, itching of nose, itching of throat, itchy watering eyes due to upper respiratory allergy, insomnia, sleepiness, fatigue and drowsiness.

92. The method of claim 91 wherein said nutritional supplement is a mineral, and said discomfort reliever is ibuprofen, naproxen, caffeine, acetaminophen or aspirin.

93. The method of claim 91 wherein said nutritional supplement is a calcium, and said discomfort reliever is ibuprofen, naproxen, caffeine, acetaminophen or aspirin.

94. The method of claim 93 wherein said percent daily value is between one percent and fifty percent.

APPENDIX B

THE REAL VITAMIN & MINERAL BOOK

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mented group responded to treatment, with a total disappearance of cysts and tenderness in 38 percent of the patients. My patients with fibrocystic disease have responded beautifully when vitamin E supplements were included in their health program.

Vitamin E also helps alleviate the symptoms associated with premenstrual syndrome (PMS). Many of my female patients have enjoyed marked improvement in their PMS symptoms in as short a period of time as two months. Studies also indicate that vitamin E supplementation may be useful for treating excess bleeding due to insertion of an intrauterine device. Many practicioners, myself included, have also had excellent results using vitamin E supplementation to reduce the incidence of "hot flashes" in menopausal women.

Other Uses

New functions and uses of vitamin E are being discovered all the time. In two studies, vitamin E has been shown to reduce the need for insulin in diabetes by improving insulin function and reducing the oxidative stress that leads to many of the side effects of diabetes, including vascular disease and atherosclerosis. Vitamin E, along with vitamin C and beta-carotene, may also protect against cataracts. A 1991 study of 350 men and women found that people who took daily supplements of more than 400 international units of vitamin E per day had less than half the risk of developing cataracts than did people who took no supplements. Finally, there is some evidence that vitamin E may be helpful in the treatment of lipofuscin—"age" or "liver" spots.

RDIs AND CLASSIC DEFICIENCY SYMPTOMS

Classic vitamin E deficiency symptoms include anemia caused by the premature aging and death of red blood cells, neurological disturbances such as difficulty in walking, and fragile capillaries. These symptoms generally appear only when there is the severe fat malabsorption that occurs in premature infants, or in people with disorders of the pancreas, tropical sprue, celiac disease, and cystic fibrosis. Vitamin E-deficient premature infants may also suffer from disorders of the retina, which can lead to blindness. The RDI to prevent these overt deficiencies is approximately 30 international units for men and women.

New data suggests that many people without severe fat malabsorption problems are at risk for prolonged marginal vitamin E intake, which may influence aging, cancer, and heart disease. In recent years, we've all been told to reduce our consumption of saturated fats, such as butter, and to increase our consumption of polyunsaturated fats, such as vegetable oil and margarine. This increase in PUFA is supposed to reduce the risk of coronary disease, but it also increases our need for protective vitamin E. Since the vegetable oils

that are high in PUFA are also naturally high in protective vitamin E, this would seem to pose no problem. However, *most of the commercial polyunsaturated oils are so highly processed, there is very little vitamin E left.* So while we are increasing our PUFA consumption, we are not correspondingly increasing our intake of vitamin E, a situation that has many implications. For example, some studies have suggested that people who ingest high amounts of processed polyunsaturated vegetable oils with inadequate amounts of vitamin E may have a higher risk of cancer in general, and of breast cancer in particular.

Food Sources: Vitamin E generally occurs in the fats of vegetable foods. Natural (unprocessed) vegetable oils are a particularly rich source of vitamin E, with cottonseed, corn, soybean, safflower, and wheat germ oil having the highest concentrations. Smaller amounts of vitamin E are found in whole grains, dark green leafy vegetables, nuts, and legumes. Animal foods, such as meat and dairy products, have some vitamin E, but generally are low in this nutrient.

Cooking and processing cause foods to lose their vitamin E, since it is destroyed by heat, alkalis, light, air, and freezing. The milling of grains, for example, causes a loss of about 80 percent of the grain's vitamin E. As mentioned earlier, commercially processed vegetable oils are also low in vitamin E. In fact, the by-products of processed oils have become important sources for the production of vitamin E supplements! If you depend on vegetable oils for your vitamin E, choose cold-pressed or unrefined oils.

SUPPLEMENTS

Vitamin E actually consists of eight substances, of which alpha-, beta-, delta-, and gamma-tocopherol are the most active. There are natural and synthetic forms of all the tocopherols. The naturally occurring form of vitamin E is the "D" form, as in D-alpha tocopherol. The synthetic form is the "DL" form, as in D,L-alpha tocopherol, which contains only a small proportion of natural vitamin E. The natural form appears to be the most absorbable, and recent studies indicate that it is also the most potent (bioavailable). A supplement containing D,L tocopherol supplies only an eighth to a half of the bioavailable vitamin E found in a comparable natural supplement.

Vitamin E supplements often contain alpha-tocopherols alone, because that has been shown to be the most active form. However, many nutritionists recommend that you buy your tocopherols "mixed," since that is how they exist in food.

Vitamin E succinate is a synthetic vitamin that comes in a dry, oil-free powder. Since it is the water miscible (water soluble) form of vitamin E, it can be tolerated by people who have a problem with fat malabsorption. Vitamin

This data suggests that an optimum intake for humans may be 1,000 milligrams or more daily—an amount far higher than the RDI of 60 milligrams!

Food Sources: The foods that are highest in vitamin C include broccoli, Brussels sprouts, black currants, collards, guava, horseradish, kale, turnip greens, parsley, and sweet peppers. Also high on the list are cabbage, cauliflower, chives, kohlrabi, orange pulp, lemon pulp, mustard greens, beet greens, papaya, spinach, strawberries, and watercress. Sources of moderate amounts of ascorbic acid are asparagus, lima beans, Swiss chard, gooseberries, red currants, grapefruit, limes, loganberries, melons, okra, tangerines, potatoes, and turnips. (Notice that citrus fruits such as oranges and grapefruits do not have the highest ascorbic acid content; however, their skin is high in bioflavonoids, substances that increase the amount of vitamin C that is absorbed.)

Ascorbic acid is easily destroyed when exposed to oxygen, and this process is accelerated by light and heat. Vegetables begin to lose vitamin C as soon as they are cut. Freshly squeezed orange juice, which is not likely to be that high in vitamin C in the first place, quickly begins to lose its supply of this nutrient, too. As a result, there is almost no vitamin C to speak of in the juice sold in bottles and cartons. Since vitamin C is sensitive to heat and is lost when large quantities of water are used in cooking, vegetables should be eaten raw, lightly steamed, or cooked in a small amount of water to retain the greatest amount of this nutrient.

SUPPLEMENTS

Vitamin C supplements are available both as ascorbic acid and as mineral ascorbates. You should be aware that the vitamin C in most supplements has been synthesized from natural, inexpensive substances such as starch, molasses, or sago palm. The "natural" vitamin C found in supplements is extracted from rose hips, which contain one percent ascorbic acid. Rose-hips vitamin C supplements actually contain mostly synthetic vitamin C, as a vitamin C supplement made entirely from rose hips would be enormous in size and very expensive. However, rose hips probably contain complementary substances that enhance the absorption of the vitamin, so that there may be some advantage to taking supplements which contain them. I do recommend that you buy ascorbic acid supplements which contain bioflavonoids (see Chapter 35), as these substances have been shown to increase vitamin C absorption.

In some supplements, ascorbic acid has been mixed with minerals to form mineral ascorbates. The most readily available mineral ascorbate is calcium ascorbate, which is sometimes mixed with other mineral ascorbates, such as magnesium ascorbate and sodium ascorbate. The advantage of calcium and other mineral ascorbates is that these are buffered forms of vitamin C—a desirable trait for some individuals, because they are nonacid and gentler to the stomach. People who have difficulty with oral doses of straight ascorbic acid can use these buffered products without getting acid stomach or diarrhea.

Vitamin C is widely available in the form of chewable tablets. Although convenient, high intakes of these tablets are not recommended for two reasons. First, they are usually loaded with sugar. Second, they may cause the pH of the saliva to fall so low that calcium is leached from tooth enamel.

Ascorbic acid is also available in the form of a powder that is to be dissolved in liquids. Although cheaper than tablets and capsules, the powder is less convenient to take. In addition, it, too, can damage tooth enamel, and so should be sipped through a straw if high dosages are taken frequently during the day.

OPTIMUM DAILY INTAKE—ODI

For optimum general health, the basic Optimum Daily Intake for vitamin C is:

500–5,000 mg for men and women
(along with 500–5,000 mg bioflavonoids)

Based on a thorough scientific review of vitamin C, and on my clinical experience, the following amounts of vitamin C appear to be valuable for:

Condition	Suggested Dosage
Allergies or asthma	3,000–7,000 mg
Bleeding gums	1,000–3,000 mg
Cancer prevention	5,000–10,000 mg
Coronary heart disease prevention	500–4,000 mg
Enhanced immunity	1,000–5,000 mg
Exposure to cigarette smoke and polluted air	1,000–5,000 mg
High levels of stress	1,000–5,000 mg
Surgery, wounds, injuries	5,000–10,000 mg

Your Optimum Daily Intake may vary from day to day, depending on various factors. For example, you may want to raise your intake temporarily during times of stress, or when you have a cold or another type of infection. After such a period of time, remember to decrease your supplementation *gradually* until it is back to your normal ODI.